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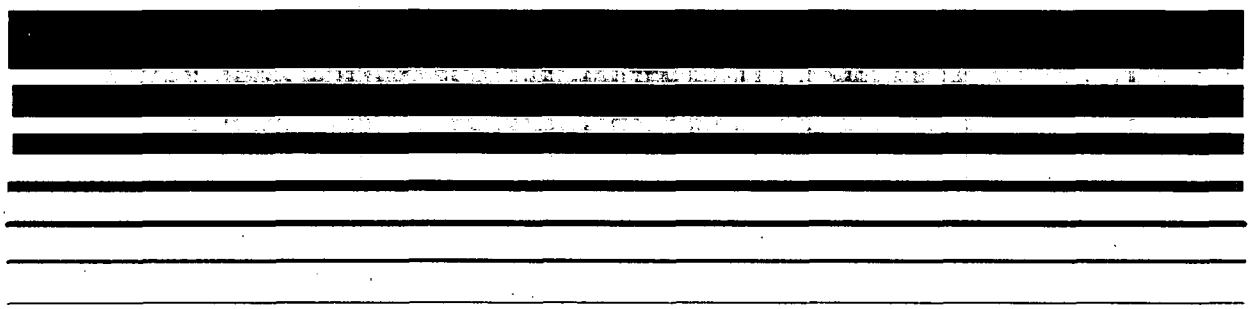
Air

EPA

Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations

Background Information for Final Standards: Summary of Public Comments and Responses



NESHAP

NATIONAL EMISSIONS STANDARDS FOR COMMERCIAL STERILIZATION AND FUMIGATION FACILITIES --

BACKGROUND INFORMATION FOR FINAL STANDARDS

NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR COMMERCIAL STERILIZATION AND FUMIGATION FACILITIES-- BACKGROUND INFORMATION FOR FINAL STANDARDS

Summary of Public Comments and Responses

Emissions Standards Division

U. S. Environmental Protection Agency
Office of Air and Radiation
Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

November 1994

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Publication No. EPA-453/R-94-084b

ENVIRONMENTAL PROTECTION AGENCY

Background Information for Final Standards
Commercial Sterilization/Fumigation Operations

Prepared by:

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Research Triangle Park, North Carolina 27711

11/18/94
(Date)

1. The final national emissions standard limits emissions of ethylene oxide from existing and new commercial sterilization/fumigation operations. The final standards implement Section 112 of the Clean air Act as amended in 1990 and are based on the Administrator's determination of July 16, 1992 (57 FR 31576) that commercial sterilization sources generate a large amount of ethylene oxide, a hazardous air pollutant listed in Section 112(b) of the Act.

2. Copies of this document have been sent to the following Federal Departments: Labor, Health and Human Services, Defense, Transportation, Agriculture, Commerce, Interior, and Energy; the National Science Foundation; the Council on Environmental Quality; members of the State and Territorial Air Pollution Program Administrators; the Association of Local Air Pollution Control Officials; EPA Regional Administrators; Office of Management and Budget; and other interested parties.

3. For additional information contact:

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4. Copies of this document may be obtained from:

   U.S. EPA Library (MD-35)
   Research Triangle Park, North Carolina 27711

   Technology Transfer Network
   Telephone No. for data transfer: (919) 541-5742
   Telephone No. for information: (919) 541-5384

   National Technical Information Service
   5285 Port Royal Road
   Springfield, Virginia 22161

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1.0 SUMMARY

On March 7, 1994, the Environmental Protection Agency (EPA) proposed national emissions standards for hazardous air pollutants (NESHAP) for commercial sterilization and fumigation operations (59 FR 10591) under authority of § 112 of the amended Clean Air Act (Act). Public comments were requested on the proposal in the Federal Register. There were 19 commenters composed of States, environmental groups, control equipment vendors, trade groups, and commercial sterilizer owners/operators.

The comments that were submitted along with responses to these comments are summarized in this document. The summary of comments and responses serves as the basis for the revisions made to the standards between proposal and promulgation.

1.1 SUMMARY OF IMPACTS OF PROMULGATED ACTION

These standards will reduce nationwide emissions of hazardous air pollutants (HAP) from commercial ethylene oxide sterilization and fumigation operations by 1,030 megagrams (Mg) (1,140 tons), or by 96 percent, in 1997 compared to the emissions that would result in the absence of the standards.[1] The standards for sterilization chamber vent and aeration room vent emissions are unchanged from those in the proposed preamble [950 Mg (1,050 tons) and 48 Mg (53 tons), respectively] [as published in the Federal Register on March 7, 1994, (59 FR 10595)]. The standards for chamber exhaust vent emissions account for a nationwide reduction of 34 Mg (37 tons) in 1997.[1] No significant adverse secondary air impacts, water, solid waste, or energy impacts are anticipated from the promulgation of these standards (59 FR 10595-10596).

Implementation of this regulation is expected to result in nationwide annualized costs for existing ethylene oxide commercial sterilization facilities of about $6.6 million beyond baseline.[2] Capital cost incurred by a typical uncontrolled existing source such as a large commercial sterilization and fumigation operation using 68,000 kilograms per year (kg/yr) [(75 tons per year (tons/yr)] of ethylene oxide would be about $310,000 for controlling the sterilization chamber vent emissions (unchanged since proposal, see 59 FR 10596) and about $290,000 for controlling the aeration room vent and chamber exhaust vent emissions.[2] The annualized cost incurred by this typical source to operate the control devices would be about $100,000 for the sterilization chamber vent (unchanged since proposal, see 59 FR 10596) and about $80,000 for the aeration room vent and chamber exhaust vent.[2] The costing analysis is summarized and can be found in detail in Chapter 7 of the background information for proposed standards[3] and changes to capital and annualized costs since proposal are provided in reference 2.

The economic impact analysis done prior to proposal showed that the economic impacts from the proposed standards would not be significant (59 FR 10596). No changes have been made to the promulgated rule since proposal that would increase the economic impacts to a significant level. The economic impact analysis is summarized in the proposal preamble (59 FR 10596) and a detailed discussion can be found in Chapter 8 of the background information for proposed standards.[3]

1.2 SUMMARY OF CHANGES TO THE MACT FLOOR FOR MAJOR SOURCE CHAMBER EXHAUST VENTS[4]

The only major change to the regulation from its proposal is the reevaluation of the MACT floor for major source chamber exhaust vents. A general discussion of the MACT floor determination is given in the preamble to the proposed rule (59 FR 10592-10593). Information submitted by commenters on the proposed regulation indicated that a controlled MACT floor exists for existing major source chamber exhaust vents. The control of these vents involved the ducting of the emissions from the

chamber exhaust to a control device installed to control aeration room vent emissions. For a source that controls aeration room vent emissions already, the emissions from the chamber exhaust vent are manifolded to this control device. To facilitate combined control of the two emissions points, the air flow rate from the aeration room to the control device is reduced when control of emissions from the chamber exhaust vent is necessary. This combined flow option for use with an existing control device may also be used for manifolding the chamber exhaust vent emissions to the sterilization chamber vent control device.

Because there are approximately 50 major sources contained in the Agency's commercial sterilization data base, the best controlled six facilities (12 percent) comprise the MACT floor. The Agency therefore contacted six facilities that commenters listed as controlling chamber exhaust vent emissions to ascertain their major source status. Each of these six facilities indicated that they were a major source (annual ethylene oxide use of 20,000 pounds or more). While commenters reported emissions reduction information for these sources, the efficiencies reported reflect the efficiency achieved by the control device to which multiple vent emissions are vented; the emissions reductions achieved for the chamber exhaust vent emissions were not verified with actual test data. Therefore, the MACT floor for the chamber exhaust vent at existing major source commercial ethylene oxide sterilization and fumigation operations is control of the chamber exhaust vent. The best controlled similar source controls emissions from the chamber exhaust vent, and the MACT floor for new major sources is therefore control of the chamber exhaust vent emissions. The emissions from the chamber exhaust vent at both new and existing major sources either must be vented (manifolded) to a control device achieving 99 percent emissions reduction that controls the emissions from either the aeration room or sterilization chamber vent control device or must be vented to a dedicated control device that achieves at least 99 percent emissions reduction.

1.3 SUMMARY OF CHANGES SINCE PROPOSAL

Several changes have been made since the proposal of these standards in response to public comments. The majority of the changes have been made to clarify portions of the rule that were unclear to the commenters. Other changes include reassessment of the MACT floor for the chamber exhaust vent, addition of another referenced control technology, allowing alternative monitoring scenarios, and extending the compliance period for all sources. All changes that have been made to the regulation are fully explained in the responses to the comments. A summary of the requirements for each emissions source is outlined below and contains the following information: (1) changes to the requirements since proposal have been identified in the outline along with the section of this background information document (BID) containing the discussion and rationale for the change, and (2) in instances where no changes have been made to the regulation since proposal, a reference has been identified for locating the rationale used in determining the requirements.

OUTLINE-MAJOR CHANGES TO REGULATION SINCE PROPOSAL

I. STERILIZATION CHAMBER VENT

A. Standards for Sterilization Chamber Vents

No change in the level of the standards for major and area sources from proposal on March 7, 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01), pp. 10597-10600 for rationale.]

B. Format of the Standards for Sterilization Chamber Vents

No change in the format of the standards from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale.]

C. Compliance and Performance Testing for Sterilization Chamber Vent

The monitoring parameters for the control devices at both major and area sources have changed from proposal in March 1994 as follows:

1. For acid-water scrubbers, the monitoring requirement has changed from continuously monitoring the ethylene glycol in the

proposed rule to weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank in the final rule. (See Section 2.4.2.)

2. For oxidation units, the monitoring requirement has changed from continuously monitoring the temperature within a specific range (±10°F) in the proposed rule to continuously monitoring a minimum baseline temperature in the final rule. (See Section 2.4.3.)

II. AERATION ROOM VENT

A. Standard for Aeration Room Vent

1. Existing and New Major Sources. No change in the level of the standards from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10597-10598 for rationale.]

2. New Area Sources. No change in the level of the standard from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10598-10599 for rationale.]

3. Existing Area Sources. Information submitted by commenters indicated that existing area sources are controlling emissions from the aeration room vent; there are at least eight (12 percent of 68) facilities known to control aeration room vent emissions. The MACT floor for existing area sources for aeration room vents is control.[5] Just as MACT was rejected and GACT was selected based on cost effectiveness of over $100,000/ton for new area sources, the Administrator explained in the preamble to the proposed rule that if information was submitted indicating a controlled floor for existing area sources, MACT would be rejected and GACT selected for existing area sources. Due to the high cost effectiveness associated with control of existing area source aeration room vents, MACT has been rejected and GACT selected for this source category; GACT for this source category is no control. [See Section 2.2.6 and see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10599-10600 for rationale.]

B. Format of the Standard for Aeration Room Vent

1. Major Sources. The final rule provides additional flexibility to facilities by allowing sources to comply with either the 1 part per million volume (ppmv) concentration limitation as proposed [see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale] or a 99 percent emissions reduction (based on commenters' suggestions, see Section 2.2.6).

2. Area Sources. No control; no change from proposal in March 1994.

C. Compliance and Performance Testing for Aeration Room Vents

1. Major Sources. Facilities may demonstrate compliance by continuously monitoring either the ethylene oxide concentration from the aeration room vent after the control device as proposed or by parametrically monitoring the control device achieving 99 percent emissions reduction. The monitoring parameters for demonstrating compliance are as follows [same as listed above in Sterilization Chamber Vent]: for oxidation units, the monitoring requirement has changed from continuously monitoring the temperature within a specific range (±10°F) in the proposed rule to continuously monitoring a minimum baseline temperature in the final rule. (See Section 2.4.3.)

2. Area Sources. No control and therefore no compliance requirements are necessary; no change from proposal in March 1994.

III. CHAMBER EXHAUST VENTS

A. Standard for Chamber Exhaust Vent

1. Major Sources. Based on information submitted by commenters and subsequent followup, there are at least six (12 percent of 50) existing major sources known to control chamber exhaust vent emissions by manifolding emissions to a sterilization chamber vent or aeration room vent control device (see Section 2.2.7). The MACT floor for existing major sources for chamber exhaust vents is control of chamber exhaust vent emissions by a control device. The best controlled source controls emissions from the chamber exhaust vent by venting to a

control device; the MACT floor for new sources is therefore control of chamber exhaust vent emissions.[4] (See § 112(d) of the Act) The standard for chamber exhaust vents specifies that a facility may either manifold the emissions to controls for the sterilization chamber vent or the aeration room vent or may reduce emissions by 99 percent. (See Section 2.2.7.)

2. Area Sources. No control but facilities must demonstrate that the source is under the 5,300 ppmv concentration limit; no change from proposal in March 1994. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10598-10600 for rationale.] Additional flexibility has been added to the standard in that sources may choose to demonstrate control by reducing emissions by 99 percent. (See Section 2.2.7.)

B. Format of the Standard for Chamber Exhaust Vent

1. Major Sources. Sources will comply by venting to a device achieving a 99 percent emissions reduction. The percent emissions reduction is consistent with the data submitted by commenters for control devices the emissions are vented to and as is consistent with the format for both the SCV and the ARV standards (for manifolding purposes). (See Section 2.2.7.)

2. Area Sources. The final rule provides flexibility to facilities by allowing sources to comply with the concentration limit as proposed [see 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10600-10601 for rationale] or with a 99 percent emissions reduction limitation (see Section 2.2.7).

C. Compliance and Performance Testing for Chamber Exhaust Vent

1. Major Sources. Sources that manifold emissions would determine the monitoring parameters based on the initial compliance test and the parameters determined for the sterilization chamber vent or the aeration room vent control device. Sources with dedicated control devices would determine the monitoring parameters based on the control technology used.

The monitoring parameters for dedicated control devices are as follows [same as listed above in SCV]:

- for acid-water scrubbers, the requirement is weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank. (See Section 2.4.2.)

- for oxidation units, the requirement is continuously monitoring a minimum baseline temperature. (See Section 2.4.3.)

2. Area Sources. Facilities must demonstrate that there are no increases in emissions from the chamber exhaust vent by either monitoring the ethylene oxide concentration in the sterilization chamber prior to activation of the chamber exhaust or by controlling the emissions from this vent. A facility may choose to comply with the 5,300 ppmv limitation by manifolding the emissions to a control device for the sterilization chamber vent or controlling the emissions with a dedicated control device. Sources that manifold emissions would determine the monitoring parameters based on the initial compliance test and the parameters determined for the sterilization chamber vent. Sources with dedicated control devices would determine the monitoring parameters based on the control technology used.

The monitoring parameters for the dedicated control devices are as follows [same as listed above sterilization chamber vents]:

- for acid-water scrubbers, the requirement is weekly monitoring of either the ethylene glycol concentration or the level of scrubber liquor in the scrubber liquor tank. (See Section 2.4.2.)

- for oxidation units, the requirement is continuously monitoring a minimum baseline temperature. (See Section 2.4.3.)

IV. IMPACTS FOR THE PROMULGATED REGULATION

A. Air. Additional ethylene oxide emissions reduction is achieved by controlling emissions from major source chamber exhaust vents (see Section 2.2.7); the nationwide emissions reduction increases from 93 percent (1,100 tons) reduction anticipated in the proposed rule [see 59 FR 10591 (EPA Air

Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10595 for rationale] to 96 percent (1,140 tons) reduction anticipated in the final rule.[1]

B. Water, Solid Waste, Noise. Minimal change from the impacts discussed in the preamble to the proposed rule. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10596 for rationale.]

C. Energy. Minimal change from the impacts discussed in the preamble to the proposed rule. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), p. 10596 for rationale.]

D. Cost. The combination of aeration room vent and chamber exhaust vent control costs is approximately $290,000 at a typical source, an increase of $20,000 from the $270,000 average facility cost for controlling only the aeration room vent (increase over proposal costs for the aeration room vent due to duct work for the chamber exhaust vent); total nationwide costs increased from $6.4 million to $6.6 million.[2]

E. Economic. Not a significant regulation per Executive Order 12866 (58 FR 51735); minimal change from proposal. [See 59 FR 10591 (EPA Air Docket A-88-03, Docket Entry III-A-01 and III-A-02), pp. 10604-10605 for rationale.]

V. MISCELLANEOUS

A. The compliance time for all sources has been extended from 2 to 3 years. This extension has been provided to allow sources additional time in complying with these standards. New sources with startup after the 3 year compliance date will be required to comply upon startup of the source.

B. Several commenters requested clarification of General Provisions requirements as they relate to this rule. A table identifying the relationship of the final General Provisions requirements has been added to the final rule. Language similar to that contained in the General Provisions has been added to this regulation in cases where a direct reference to the General Provisions was not appropriate.

C. Reporting of excess emissions is required semiannually, whether the source has experienced excess emissions or not; the Administrator may determine on a case basis that more frequent reporting is necessary.

1.4 REFERENCES

1. U. S. Environmental Protection Agency. Ethylene Oxide Commercial Sterilization Data Base. Research Triangle Park, North Carolina. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-A-01.

2. Memorandum from Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 24, 1994. Costing of Controls for the Chamber Exhaust Vent. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-03.

3. U. S. Environmental Protection Agency. Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations, Background Information for Proposed Standards. Draft EIS. October 1992. U. S. Environmental Protection Agency Publication No. EPA-453/D-93-016. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry II-A-22.

4. Memorandum from Hearne, D.G., and Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 24, 1994. Revised Calculation of MACT Floors for Major Source Chamber Exhaust Vents at Ethylene Oxide Commercial Sterilization and Fumigation Operations. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-02.

5. Memorandum from Schmidtke, K.L., Midwest Research Institute to Markwordt, D.W., EPA/CPB/CMS. October 27, 1994. Revised Calculation of the MACT Floor for Area Source Aeration Room Vents. U. S. Environmental Protection Agency Air Docket A-88-03, Docket Entry IV-B-05.

2.0 SUMMARY OF PUBLIC COMMENTS

A total of 18 letters commenting on the proposed rule and the BID for the proposed standards were received during the public comment period. Two comments were received after the close of the comment period and were considered in finalizing the regulation. A list of commenters, their affiliations, and the EPA tracking number assigned to their correspondence is given in Table 2-1.

For the purpose of presentation, the comments have been categorized under the following topics:

1. Selection of Source Categories to be Regulated;
2. Regulatory Approach;
3. Compliance Dates;
4. Monitoring Requirements;
5. Test Methods;
6. Reporting and Recordkeeping Requirements;
7. Wording of the Regulation; and
8. Miscellaneous

2.1 SELECTION OF SOURCE CATEGORIES TO BE REGULATED

2.1.1 Source Type

Comment: One commenter (10) expressed concern that EPA has not addressed ethylene oxide storage areas and the point where the ethylene oxide storage tank is connected to the sterilization unit as possible emissions points. At a minimum, EPA should prevent uncontrolled venting of the unused ethylene oxide from the tank. One commenter (19) stated that the final rule should address equipment leaks and sterilizer door hood exhaust emissions. The commenter indicated that these emissions points are addressed by regulations in California.

TABLE 2-1. COMMENTS RECEIVED ON THE PROPOSED EO STERILIZATION NESHAP

Docket Item[a]	Commenter and Affiliation
IV-D-01	David Driesen Natural Resources Defense Council 1350 New York Avenue, Northwest Washington, DC 20005
IV-D-02	John Walton Tennessee Department of Environment and Conservation Tennessee Air Pollution Control Board 9th Floor, L & C Annex 401 Church Street Nashville, TN 37243-1531
IV-D-03	Margaret Corbin Puget Sound Air Pollution Control Agency 110 Union Street, Suite 500 Seattle, WA 98101-2038
IV-D-04	Ann Baldwin Health Industry Manufacturers Association 1200 G Street, Northwest Suite 400 Washington, DC 20005-3814
IV-D-05	Gary Wilson COBE Laboratories, Inc. Environmental Health and Safety 1185 Oak Street Lakewood, CO 80215
IV-D-06a[b]	Robert Wheeler SIMS Concord/Portex Technical Services 15 Kit Street Keene, NH 03431
IV-D-06b[b]	Allen Ammerman Griffith Micro Science 200 S. Frontage Road, Suite 120 Burr Ridge, IL 60521-6916
IV-D-07	Michael Pucci AT&T Corporate Environment and Safety Engineering Center 131 Morristown Road Basking Ridge, NJ 07920
IV-D-08	Raymond Connor Manufacturers of Emission Controls Association 1707 L Street, Northwest Suite 570 Washington, DC 20036-4201

TABLE 2-1. (continued)

Docket Item[a]	Commenter and Affiliation
IV-D-09	David Mixon McCormick and Company, Inc. 18 Loveton Circle Post Office Box 6000 Sparks, MD 21152-6000
IV-D-10	Thomas Allen New York State Department of Environmental Conservation Division of Air Resources 50 Wolf Road Albany, NY 12233-3254
IV-D-11	Cary Olson Donaldson Company, Inc. Chemical and Catalytic Systems Post Office Box 1299 Minneapolis, MN 55440-1299
IV-D-12	Gerald Messerschmidt C. R. Bard, Inc. Scientific Affairs 730 Central Avenue Murray Hill, NJ 07974
IV-D-13	William O'Sullivan New Jersey Department of Environmental Protection and Energy Air Quality Regulation Program 401 East State Street Trenton, NJ 08625
IV-D-14	Michael Wax Institute of Clean Air Companies 1707 L Street, Northwest Suite 570 Washington, DC 20036-4201
IV-D-15	Barbara Morin Rhode Island Department of Environmental Management Division of Air Resources 291 Promenade Street Providence, RI 02908-5767
IV-D-16	Patricia Leyden South Coast Air Quality Management District (SCAQMD) 21865 E. Copley Drive Diamond Bar, CA 91765-4182

TABLE 2-1. (continued)

Docket Item[a]	Commenter and Affiliation
IV-D-17	Robert Colby Donald Theiler STAPPA/ALAPCO 444 North Capitol Street, Northwest Washington, DC 20001
IV-D-18[c]	Bay Area Air Quality Management District (BAAQMD) 939 Ellis Street San Francisco, CA 94109
IV-D-19[c]	Deborah Sheiman Natural Resources Defense Council 1350 New York Avenue, Northwest Washington, DC 20005

[a]The docket number for the commercial sterilization and fumigation docket is A-88-03.
[b]This designation for internal use only, these comments were assigned identical docket numbers by EPA's Air and Radiation Docket and Information Center.
[c]This designation for internal use only, these comments were received after the close of the comment period and have not been assigned a docket number.

One commenter (17) stated that fugitive leak emissions should be addressed in these standards. One commenter (18) stated that a separate standard based on leak monitoring should be established to address equipment leaks. This commenter and one other (03) recommended that the regulation should address leak detection and repair (LDAR) and prohibit operation of a sterilizer (03, 18) or aerator (03) unless the maximum concentration of ethylene oxide as measured 1 centimeter away from any portion of the equipment, with an FID calibrated with methane or other approved gas (18), is less than 10 ppmv.

Response: The main fugitive emissions point for sterilization and fumigation operations is the sterilization chamber door. The chamber door is opened slightly prior to unloading products from the sterilization chamber, and this opened door is an emissions point that must be properly ventilated in order to meet OSHA standards to reduce worker exposure to ethylene oxide. The OSHA requirement specifies that the level of exposure to workers not exceed 1 ppmv or 1.8 mg/m^3 ethylene oxide over a normal 8-hour (hr) workday and 40-hr workweek. Emissions from the opened chamber door are typically vented automatically by the chamber exhaust vent. Emissions from the other fugitive emissions points listed by the commenters are addressed by the OSHA standards for ethylene oxide sources and are negligible. The Agency believes that the OSHA requirements limiting worker exposure to a maximum of 1 ppmv ethylene oxide should be sufficient to limit these fugitive emissions points and protect employees. Based on additional data submitted by a commenter, the chamber exhaust vent will be controlled at both existing and new major sources (see Section 2.2.7).

In the Agency's experience, venting of ethylene oxide from the storage tanks is not practiced, and the Agency has received no evidence to show that uncontrolled venting occurs. The Agency believes that common practice for handling empty or nearly empty ethylene oxide tanks includes closing the valve at the outlet of the tank, removing the tank from the line to the sterilization

chamber, and returning the tank to the chemical company or supplier for reuse.

Comment: One commenter (10) stated that the standards for the sterilization chamber vent should be written to specifically delineate that the ethylene oxide drain emissions are to be eliminated by use of a closed-loop, recirculating vacuum pump drain and that these emissions are to be included with the sterilization chamber vent emissions and are subject to the 99 percent control requirement. Another commenter (03) also requested that a clear statement that it is unlawful to cause or allow discharge of ethylene oxide to the wastewater stream from the sterilizer exhaust pump working fluid be included in the rule. Another (19) also stated that the final rule should address vacuum pump drain emissions.

One commenter (06b) supported EPA's proposed requirements for the sterilizer vacuum pump.

Response: The background information document for the proposed standards identifies emissions from wastewater associated with the use of once-through vacuum pumps as a component of the sterilization chamber vent emissions stream. Under the proposed rule, the emissions from this entire stream are to be reduced by 99 percent. The proposed regulation therefore provides sources with the flexibility to convert to a closed-loop vacuum pump (a recirculating fluid pump that has no wastewater emissions) or retain the once-through pump and choose to control the wastewater emissions of ethylene oxide by some other method. However, because the definition of sterilization chamber vent includes emissions from any vacuum pump used, the control efficiency of these vacuum pump drain emissions must be included in the overall calculation for 99 percent emissions reduction required for this vent. The Agency does not believe that an equipment-based standard such as the commenter suggests is necessary for the vacuum pump emissions to achieve a 99 percent reduction in emissions.

Comment: Two commenters (04, 07) supported the exemptions for research and laboratory facilities. One of these commenters

(04) stated that the regulation should not apply to research and development vessels located at commercial sterilization facilities, provided they meet the other requirements of § 63.360. The commenter stated that companies should not be penalized for locating small research and development units at a site where commercial sterilization occurs. The commenter added that these units would be exempt from the proposed rule if they were located at different sites. The commenter noted that this is particularly onerous if the research and development units are located in a different part of the site from the commercial scale units and cannot utilize the same control device. Another commenter (18) also requested that EPA clarify the application of § 63.360(e) to include in the exemption research and development installations on the site of manufacturing facilities and for profit facilities that perform contract research (e.g., product testing) as their primary "product."

Two commenters (05, 10) indicated that the regulation should apply to research and laboratory facilities. One commenter (05) stated that the rule should be expanded to include research and development vessels, provided the vessels meet the other requirements of § 63.360. Another commenter (11) stated the rule should include any research or laboratory facility that uses more than the limit established in § 63.360(c). This commenter also stated that these vessels are generally used to validate process parameters for the production and sterilization of medical components and, as such, are part of the manufacturing process, not a true R&D function. This commenter also indicated that the cost to control such equipment, because of its small size and low usage, is minimal. Costs for equipment would range from $15,000 to $65,000 and should not create an economic hardship for a manufacturer even if the sterilizer is located remotely from the main manufacturing unit.

Response: Section 112(c)(7) of the Act requires the Administrator to establish a separate category for research and laboratory facilities. Sources that engage in purely research and development activities are exempt from this regulation,

however, all sterilization chambers located at commercial sterilization facilities that are otherwise an affected source are not exempt from the final rule. Sterilization chambers used to develop pressure, temperature, and humidity settings are considered part of the process procedure and are not considered to be research or laboratory operations as defined in the Act.

Comment: One commenter (07) supported the exemptions for medical services facilities.

Seven commenters (03, 10, 11, 15, 16, 17, 19) suggested that the rule should apply to medical care facilities. One of these commenters (10) indicated that their state is attempting to locate, control, and permit all sources of ethylene oxide. This state controls hospital sources, which typically have low release heights and are located in urban areas, because exposure and the associated effect on health would be great. This commenter also stated that exempting hospital sterilizers would prevent the regulation of a large amount of ethylene oxide which would have a significant effect on health. Another commenter (17) noted that in several states, many significant sources would be exempt from the standards as written. The commenter pointed out that these sources are not only the largest ethylene oxide emitters but are often located in residential areas and are themselves the site of some of the most sensitive receptors in the population. Another of these commenters (15) indicated that hospital sterilizers are controlled in Rhode Island and that modelling of hospitals in their state has shown health impacts considerably higher than acceptable levels. The commenter added that members of the public and sensitive individuals (e.g., persons with compromised health, pregnant women, young children) are often within close proximity to hospital ethylene oxide emissions. Another commenter (03) suggested that exempting hospitals and other sources, which emit significant quantities of ethylene oxide to potentially sensitive populations, is unacceptable.

One commenter (16) stated that ethylene oxide emissions from medical facilities such as hospitals represent approximately 64 percent of the sources and 17 percent of the total ethylene

oxide emissions in California. Another commenter (10) indicated that hospital sterilizers in New York use over one-third of the total ethylene oxide used statewide. One commenter (11) indicated that the source-type exemptions and the ethylene oxide usage cutoffs in § 63.360 exempt approximately 9,000 hospitals and leave close to 600 tons/yr ethylene oxide uncontrolled, not the 15 tons/yr of ethylene oxide left uncontrolled that was presented in the preamble [the 15 tons/yr was calculated as the residual ethylene oxide emissions from commercial sterilizers after the standards].

Two commenters (10, 11) provided information regarding the economic burden of controlling ethylene oxide emissions from hospital sources. One of these commenters (11) indicated that the financial burden to a hospital is minimal as the control equipment for this segment costs between $15,000 and $35,000, depending on sterilizer size. The other commenter (10) indicated that the economic burden associated with controlling the medical services facilities has not resulted in a significant removal of sterilizers from hospitals in their state.

One commenter (17) suggested that because some distinction between hospitals and commercial interests is warranted, EPA could consider reduced administrative requirements for medical facilities. One commenter (18) stated that in the event EPA chooses to regulate hospital sterilizers using less than 1 ton/yr ethylene oxide, an exemption should be provided for sources subject to stringent State/local standards, Title V permits should not be required, and administrative requirements should be limited.

One commenter (19) stated that EPA's actions under § 112(d) should not be treated as a distinct activity wholly separate from work under § 112(k). This commenter stated that EPA should address smaller ethylene oxide sources under these standards rather than under the urban air toxics program. The commenter noted that this would be more protective of human health and the environment and reduce the level of effort required from the Agency. This commenter also stated that the proposed rule

ignores EPA's broader responsibility under the Clean Air Act to establish abatement strategies for sources of air toxics emissions in urban areas, a program that provides additional impetus and legal authority to establish lower applicability cutoffs and to regulate sterilizers located at medical institutions such as hospitals. The commenter also stated that the exempt and excluded facilities under the proposed rule typify area sources of hazardous air pollution that contribute to health risks in urban areas; control of emissions from such sources will be needed to achieve the legislative mandate to reduce cumulative exposures to hazardous air pollutants from many relatively small emissions sources. In addition, the commenter indicated that ethylene oxide is prototypical of the type of pollutant and uses that Congress directed EPA to address under the urban air toxics program and that EPA should address such pollutants and source categories under the § 112(d) standards rather than deferring control to the § 112(k) program, which is running behind schedule.

Two commenters (15, 17) stated that if hospitals are not included in this regulation, then they should be listed as a separate source category for MACT standards; one of these commenters (17) also stated these operations should be subject to later review under § 112(f). Another commenter (19) indicated that if EPA does not address hospital sterilizers under these NESHAP, hospital sterilizers should be added to the list of source categories as soon as possible and EPA should concurrently propose application of the commercial sterilizer standards to hospital sterilizers. This commenter noted that hospital sterilization was initially included on the proposed source category list but was dropped from the final source category list and that the commenter was therefore unaware that this category had been dropped until reading the definition of "commercial sterilizer" in this proposed rule and realizing that it was being defined so as to exclude hospitals. The commenter stated that EPA should broaden the definition of commercial sterilization to include hospital sterilizers. The commenter asserted that there

is no fundamental difference between ethylene oxide sterilization carried out in a commercial sterilizer as defined in the proposed rule and ethylene oxide sterilization in a hospital.

Response: The reference to hospital sterilizers was included in the regulation for clarification purposes in defining commercial sterilizers. It is important to note that sterilization at hospital facilities was not exempted in a true sense but was omitted based on the definition of commercial sterilization. The EPA originally listed "commercial sterilization facilities" and "hospital sterilization facilities" as two separate categories on the proposed source category list. These source categories by definition did not overlap. When it was decided not to include hospital sterilizers on the final source category list, only commercial sterilization facilities remained on the list. Source categories have to be on the source category list to be regulated by EPA under § 112(d) of Title III. The source category list was published on July 16, 1992 (57 FR 31576); the public was given an opportunity to review and comment on the list. Section 112(c) requires EPA to establish a list of source categories of major and area sources that emit these HAP and to promulgate regulations for each of these source categories under § 112(d); this section also specifies that the source category list will be periodically revised in response to public comment or new information. If hospitals are added to the source category list at a future date, hospital sterilizers will be placed in the 10-year promulgation bin. In addition, the majority of hospital sources emit less than 1 ton/yr. If this rule for commercial sterilization had been developed in conjunction with hospital sterilization, the majority of hospital sterilization sources would not be included due to the area source emissions exemption of 1 ton/yr (see Section 2.1.2).

The Agency believes that it is appropriate to address the urban air toxics program of § 112(k) separately from this rulemaking. The urban toxics study will include a large variety of sources; hospital sterilization sources and sources with

emissions less than 1 ton/yr will likely be assessed as part of this under § 112(k).

Because sterilization operations performed at medical facilities are not subject to these NESHAP, consideration of alternative administrative requirements and Title V issues for medical facilities is not necessary. (See Section 2.2.4 for discussion of risk and see Section 2.2.6 for discussion of § 112(f).)

Comment: One commenter (18) stated that the Agency has expanded the source category description to include fumigation operations while limiting the source category to operations that use ethylene oxide as the sterilant/fumigant. The commenter recommended that EPA provide rationale for their decision to restrict the applicability of the rule to ethylene oxide and not cover operations that use other sterilant/fumigant gases (e.g., methyl bromide) and to amend the source category description in the source category list. Another commenter (17) also suggested that other sterilants and fumigants besides ethylene oxide (e.g., methyl bromide) should be regulated under this source category, and if they are not included, then these operations using the other sterilants and fumigants should be listed as a separate source category. Another commenter (06b) questioned whether EPA will regulate manufacturers of ethylene oxide as well.

Response: The Agency would like to point out that fumigation processes have always been a part of this regulation and were not added to the source category; the Agency considers sterilization and fumigation processes to be the same, with the processes being used for eliminating microorganisms and vermin (insects), respectively. As is evident, the only HAP compound regulated in this rule for the commercial sterilization and fumigation source category is ethylene oxide. The category listed on the final source category list (57 FR 31576) for which this rule was developed relates specifically to ethylene oxide commercial sterilization processes. Other categories of sterilization facilities using other HAP as the sterilizing compound were not identified on the source category list and

therefore will not be regulated by EPA at this time. Other types of sterilization processes may be added to the source category list in the future.

While ethylene oxide production is not listed specifically on the source category list, ethylene oxide is one of approximately 400 chemicals listed in the Synthetic Organic Compound Manufacturing Industry NESHAP (SOCMI; also referred to as the Hazardous Organic NESHAP, or the HON). Manufacturers who produce ethylene oxide and emit HAP compounds as a result of this production or who use ethylene oxide as a raw material in the production of another listed SOCMI chemical are subject to the SOCMI NESHAP.

Comment: One commenter (10) noted that some States, by State law, are not able to regulate pollutant emissions more stringently than a Federal regulation. The commenter added that this would prevent these States from regulating facilities exempted in §§ 63.360(b) through (f), such as hospital sterilizers. Another commenter (17) stated that EPA should mandate strong standards on a national scale and not rely on State and local agencies to compensate with stronger measures, since some States will be precluded from going beyond Federal requirements.

One commenter (18) requested that if the sources are regulated under a stringent State or local standard, EPA should continue to exempt hospital sterilizers and small sterilizers (using less than 1 ton/yr ethylene oxide) from any otherwise applicable requirements, including Title V permitting and administrative requirements. This commenter also recommended that EPA require control of the aeration room vents unless they are required to control aeration room vent emissions under a stringent State or local requirement.

Response: There are several State and local regulations that require control of ethylene oxide emissions from commercial sterilization operations. The EPA agrees that there may be instances where the Federal emissions standards could be less stringent than a State or local standard. The NESHAP are

intended to be representative of maximum achievable control on a national basis, and the Agency recognizes that in some areas the standards may not address individual air pollution control needs. While States are prohibited from adopting standards that are less stringent, they may go beyond the Federal requirement and adopt standards that are more stringent. Certain States use Federal rules as a baseline for their own regulations and it is at the State's discretion to go beyond the Federal requirement.

The fact that a State currently regulates a particular source that is also the subject of NESHAP does not predispose those facilities to exemption from the Federal regulation and its requirements. The NESHAP apply to all major and in some instances area sources within the subject source category. However, if a source is currently controlling emissions from commercial sterilization to comply with a State or local rule, they may have sufficient control in place to meet this standard as well. In addition, reporting required for a State rule may also be submitted to fulfill the reporting requirements for the Federal rule given that all of the appropriate information is contained in the State report (i.e., ethylene oxide usage, test data, excess emissions, etc.). States will likely be delegated the authority for implementing rules for Part 63.

2.1.2 Source Size

Comment: Eight commenters (03, 10, 11, 15, 16, 17, 18, 19) requested that EPA reevaluate the emissions cutoff for area sources. These commenters pointed out that several States are requiring lower cutoffs, as low as 2.5 pounds per year (lb/yr), than the 1 ton/yr cutoff found in the proposed rule and indicated that these State regulations should be considered. One of these commenters (16) indicated that facilities with ethylene oxide emissions less than 1 ton/yr represent a large segment of the ethylene oxide emitted in its district. Another commenter (11) suggested that the emissions cutoff should be 100 lb/yr [0.05 ton/yr] for area sources. Another (19) suggested that the emissions cutoff be lowered to include sources using 4 lb/yr or more of ethylene oxide. One commenter (17) indicated that the

applicability threshold should be established to include area sources as well as sources that are considered "major."

One commenter (18) stated that EPA's justification for the 1 ton/yr cutoff (cost-effectiveness data and low emissions contribution) was not sufficient and was counter to the commenter's experience; the commenter requested a better justification for this cutoff. One commenter (19) stated that cost-effectiveness analysis is inappropriate and irrelevant to EPA's selection of an applicability cutoff. The commenter stated that the 1 ton/yr cutoff is arbitrary and inequitable, both for commercial sterilizers and for people living near ethylene oxide facilities. The commenter added that EPA's reliance on cost-effectiveness analysis to establish a regulatory cutoff of one ton is inappropriate because it does not speak to feasibility or to the actual cost to a facility or affordability of controls. The commenter referred to CARB estimates of the costs of compliance with its commercial and hospital ethylene oxide sterilization regulations indicating an annualized cost of $24,000 - costs that most small businesses would be able to absorb without significant adverse impact on their profitability. The commenter stated that the fact that controls are in place for all sterilizers down to the 4 lb/yr use level in California indicates that it is not only achievable, but also affordable, to control ethylene oxide emissions from sources under 1 ton/yr. The commenter stated that local impacts on individuals living near ethylene oxide sources should be the critical issue in determining an applicability cutoff. The commenter asserted that because there is a greater potential for human exposure from thousands of small sources located in commercial and residential areas that vent ethylene oxide directly into the atmosphere than from the few facilities that manufacture the substance, these smaller sources should be controlled under the standards.

Two commenters (10, 16) indicated that the majority of ethylene oxide sterilization and fumigation sources located in their State and district will not be subject to the proposed rule due to the combination of the ethylene oxide usage cutoff and the

source exemptions; another commenter (18) stated that the exemptions of the proposed rule apply to all ethylene oxide sterilizers in their district. One of these commenters (10) stated that, considering the large number of ethylene oxide sources and the high toxicity of this contaminant, the applicability of the final rule should be expanded so that a larger number of facilities would be controlled by this Federal MACT standard.

Two commenters (10, 11) indicated that the emissions cutoff limit for the sterilization chamber vent should be either eliminated or reduced. One of these commenters (11) pointed out that several States require controls for emissions from sterilization chamber vents for sources as low as 25 lb/yr [0.013 ton/yr]. This commenter suggested reducing the emissions cutoff to 100 lb/yr [0.05 ton/yr] for sterilization chamber vents. The other commenter (10) suggested that the emissions cutoff should be eliminated or substantially reduced.

One commenter (11) requested that the emissions cutoff for regulation of exhaust chamber vents be lowered to 5,000 lb/yr [2.5 tons/yr].

Response: The Agency believes the 1 ton/yr emissions cutoff for affected area sources is appropriate for this regulation. The Agency believes low emissions contribution and high cost effectiveness are sufficient reasons for placing the cutoff at 1 ton/yr. The EPA has considered the potential cost (including costs for monitoring, recording, and recordkeeping) to small sources by establishing a cutoff at 1 ton/yr. Emissions cutoffs for area sources are at the discretion of the Agency. The commenters presented no compelling reason to lower the cutoff for commercial sterilization area sources; in addition, the Agency received no information from commenters to support their statements regarding the impacts to the public. Sources emitting less than 1 ton/yr of ethylene oxide will continue to be exempt from requirements for the sterilization chamber, chamber exhaust, and aeration room vents. (See Section 2.2.4 for discussion of risk.)

Comment: One commenter (03) indicated that an applicability statement based on facility-wide usage [of ethylene oxide] would be appropriate and that control requirements should be based on the amount of ethylene oxide emissions; this commenter also stated that the control technology requirements should be based on technical feasibility for a facility emitting a specified amount of the pollutant, regardless of the type of facility. One commenter (17) agreed that the applicability for the rule should be based on actual usage of ethylene oxide rather than on a theoretical maximum potential-to-emit.

Another commenter (05) suggested that the potential-to-emit issue (opened to public comment and separate rulemaking in the final General Provisions) should be fast-tracked or the NESHAP for ethylene oxide should be delayed to avoid confusion and inappropriate characterization of a given source.

Response: Ethylene oxide usage data are used for "applicability" purposes in determining sources subject to the regulation. The applicability of the standards is based on actual annual ethylene oxide usage and is Federally enforceable. The provisions addressing the General Provisions in the final regulation indicate that applicability for these source categories is based on actual emissions rather than potential-to-emit. Control levels are not based on the emissions levels of the source; the control requirements for NESHAP regulation of major and area sources are based on MACT or MACT/GACT determinations. All sources subject to these NESHAP with similar ethylene oxide usage, regardless of the type of facility, are required to control at the same stringency.

2.2 REGULATORY APPROACH

2.2.1 MACT Floor Interpretation

Comment: One commenter in two comment submittals (01 and 19) stated that the Agency should average the emissions limitations achieved by the sources in the top 12 percent of a source category in order to determine the average emissions limitation of the best performing 12 percent of the existing sources. The commenter stated that EPA should not use the

88th percentile to calculate the MACT floor and supplied several instances from the legislative history of the Clean Air Act to support this statement. The commenter agrees with EPA that this matter is of great precedential importance and asserted that an incorrect interpretation of the MACT floor would increase the likelihood of more emissions remaining wholly uncontrolled in spite of MACT standard setting efforts and an increased likelihood of court intervention in determining the legislative intent of the MACT floor language.

The commenter also stated that the fact that the average yields an emissions limitation corresponding to no particular technology should not preclude its use; the MACT floor is a floor. The commenter added that in cases where the actual average does not match the most stringent emissions limitation achievable by any particular technology, EPA may properly set the MACT standard above the median; EPA has the authority to go above the floor but lacks the authority to go below the floor or to manipulate the floor to make it contrary to Congressional intent. The commenter stated that the final rule should use a straight average, not a median; if the final rule uses a median, the Agency must explain why use of a median is appropriate as a matter of statutory interpretation and provide a reasoned explanation for the decision to use the median in this case.

Response: The Agency appreciates the commenter's opinion on the determination of the MACT floor. In a March 9, 1994, Federal Register notice reopening the public comment period for determination of the MACT floor for NESHAP source categories (59 FR 11018), the Agency considered more than one interpretation of the statutory language concerning the MACT floor for existing sources and solicited comment on them. After consideration of the comments received in response to this request, the Agency published a final rule in the Federal Register on June 6, 1994, (59 FR 29196). In this final rule, the Agency determined that the MACT floor would be determined by averaging the best performing 12 percent of sources. This was the method followed in determining the MACT floor in the proposed rule and is the

method being used in determining the MACT floor in the final rule. In this notice, the Agency left open the use of the 94th percentile in cases where the average does not match a control technology.

Regarding the commenter's concern about use of the 94th percentile (median value) for determining the MACT floor, a discussion in Section 2.2.6 of additional data supplied by a commenter for area source aeration room vents indicates the MACT floor for existing area source aeration room vents is controlled. In the final rule, the MACT floor is determined based on a mean rather than a median value.

2.2.2 Technology Neutral MACT

Comment: Several commenters (08, 17 and 18) supported EPA's approach in determining MACT as technology neutral. One of these commenters (18) supported this flexibility because it would provide implementing agencies the authority (through delegation under Subpart E) to approve or deny the selected technology. Another of these commenters (17) stated that it was acceptable to allow sources to select their control methods provided they meet a specified percent reduction, which gives industry flexibility as well as an incentive to develop new control technologies. This commenter added that this flexibility must be accompanied by a mandate to sources to meet a strong performance standard.

One commenter (18) recommended that the language of § 63.362(a) should be revised to require control of ethylene oxide emissions from the sterilization chamber vent with an approved abatement device and then specify the performance of the device.

Response: The Agency appreciates the support for the development of these emissions reduction and emissions limitation standards. The Agency does not believe that it is necessary to require equipment-based standards such as one of the commenters recommends for sterilization chamber vents. The Agency has selected emissions reduction standards that provide the owner or operator the flexibility to choose how to achieve the required emissions reductions.

2.2.3 MACT Considerations for Sterilization Chamber Vents

Comment: Six commenters (10, 11, 13, 15, 18, 19) suggested that more stringent control requirements for the MACT standards are appropriate. One commenter (19) stated that they disagree with EPA's belief that there is little or no practical difference between a 99 percent control requirement and a 99.9 percent control requirement, because either standard would compel use of the same general type of control device and that the device, in actual practice, would achieve whatever reductions it is capable of, regardless of the numeric standard. The commenter asserted that a more stringent standard would lead to better operation and maintenance practices that would enhance the degree of emissions reductions achieved. The commenter stated that EPA has not set the standards based on information available from control device vendors regarding the efficiency of their control devices. The commenter referred to information from vendors indicating greater than 99.9 percent control from catalytic oxidation units. The commenter stated that based on this information and information in the BID, the final standard require 99.9 percent emissions reduction using catalytic oxidation for new sources.

One commenter (11) supplied information for sterilization facilities that indicated an emissions reduction of 99.9 percent from the sterilization chamber vent. The commenter was aware of 29 industrial units operating at this level of efficiency. One commenter (10) identified two major sources and three area sources above 1 ton/yr controlling sterilization chamber emissions by at least 99.8 to 99.9 percent. The commenter suggested that EPA contact these and other manufacturers to validate their claims and consider a higher control efficiency requirement for the sterilizer vent. The commenter stated that all sources in New York with an emissions rate potential greater than or equal to 1.0 lb/hr are required to install 99 percent control or greater or best available control technology (BACT). One commenter (15) stated that the proposed 99 percent control efficiency for sterilization chamber vent emissions is not stringent enough nor is it consistent with the requirements of

new source MACT. One commenter (18) recommended that EPA adopt a 99.9 percent level of control for existing sources subject to the NESHAP as is the case in California. The commenter stated that new source MACT for sterilization chamber vents should be set at 99.99 percent emissions reduction as this level of reduction has been shown in the BAAQMD.

One commenter (13) added that air permits issued recently in New Jersey have required a destruction efficiency of at least 99 percent, however, the annual emissions from some facilities meeting the minimum destruction efficiency requirement may be subject to additional control measures, such as improved dispersion and higher efficiency control, because of the carcinogenic risk of ethylene oxide.

Response: These NESHAP were based on the technological state of achieved emissions control (i.e., MACT for major sources, MACT and GACT for area sources). The Agency appreciates the submittal of data. Regarding the commenters' view on the establishment of the MACT floor at 99 percent emissions reduction for sterilization chamber vents, the Agency notes that the information submitted by commenters was not sufficient to demonstrate that an emissions reduction of 99.9 percent could be achieved on a continuous basis. The Agency therefore does not believe that a reassessment of MACT for the sterilization chamber vent is technically defensible. The Agency believes that the control technologies in use at the facilities the commenter is referring to (i.e., facilities achieving 99.9 percent control) are the same technologies that will be used at facilities required to meet the 99 percent standard.

Comment: One commenter (04) suggested that the use of thermal oxidizers should also be considered MACT for sterilizer chamber vents. The commenter noted that it was aware of several facilities that are using this technology to control chamber vents and that field test data from these units have demonstrated 99 percent removal efficiency as long as a stable flame is present, regardless of stack temperature.

Response: The MACT for sterilization chamber vents is 99 percent reduction of ethylene oxide emissions and is technology neutral; an owner or operator may comply with MACT by use of any technology capable of meeting the 99 percent emisson reduction efficiency. The Agency agrees that thermal oxidizers meet the reduction efficiency and has included compliance provisions for thermal oxidizers in § 63.363. The requirements of this technology are similar to those for the catalytic oxidizers; monitoring requirements are included in Section 2.4.4.

2.2.4 Role of Risk

Comment: Five commenters (10, 13, 15, 17, 19) indicated that the resulting risk from the proposed rule is unacceptable. One of these commenters (19) asserted that more stringent standards would be justified because of the extreme toxicity of ethylene oxide. This commenter also suggested the establishment of a lesser quantity cutoff [i.e., a lower emissions cutoff, because the term lesser quantity cutoff is specific to lowering of the 10 tons major source cutoff] for area sources due to the health evidence for ethylene oxide [below 1 ton/yr]. Another commenter (10) stated that the State of New York regulates all ethylene oxide emissions points under 6NYCRR Part 212 as a high toxicity contaminant. The commenter added that because of the hazardous health effects associated with exposure to small concentrations of a high toxicity contaminant, emissions points that release from 0.1 to 1.0 lb/hr are also required to install controls, and controls may be required for emissions rates less than this. This commenter provided modelling data indicating risk factors and cancer incidences for New York facilities that would result from the proposed rule:

1. For sterilization chamber vent sources with less than 1 ton/yr ethylene oxide emissions, the short-term effect results in an impact over 32,400 μg/m3 and the cancer risk for an uncontrolled 1 ton source of ethylene oxide was estimated to be over 200 in 1 million;

2. The risk factor and cancer incidence resulting from the 5,300 ppmv limit on the chamber exhaust vent are over 144,000 μg/m3 and 1 in 500, respectively;

3. The risk factors and cancer incidences resulting at a 10 tons source from the overall proposed rule include a short-term modelled impact for the three combined emissions points of over 900 μg/m3 and a cancer risk estimated to be 1 in 3,500; and

4. The short-term impacts for a source not covered by the NESHAP range from 650 to 900 μg/m3 and the cancer risk was estimated at 40 in 1 million.

Another commenter (13) stated that the New Jersey Department of Environmental Protection and Energy regulates ethylene oxide emissions as VOC's and further requires that the incremental risk of cancer posed by new and modified equipment is no more than 1 in 10,000 and preferably less than 1 in 1,000,000. This commenter estimated risk factors for EPA's proposed chamber exhaust standards and stated that this would amount to 40 lb/yr (from a facility using the least amount of ethylene oxide addressed by these standards), which for many facilities would pose more than 1 in 1 million increased cancer risk. This commenter suggested that emissions from the chamber exhaust should be controlled at major sources because of the risks posed by the amount of ethylene oxide uncontrolled from this vent. The commenter suggested that a lower concentration of about 1,000 ppmv be considered for the chamber exhaust vent standards.

One commenter (15) stated that the impacts are unacceptable without controls on aeration emissions. This commenter stated that ethylene oxide emissions in excess of 100 lb/yr result in unacceptable impacts and another (17) stated that emissions of ethylene oxide less than 1 ton/yr can pose a substantial health risk.

Response: The Agency has considered the data submitted by commenters regarding the risk of ethylene oxide related to the regulation. While risk may be considered in some determinations related to this rule, such as including area sources on the

source category list, it is important to note that these NESHAP are technology-based standards and are determined by the maximum emissions reduction achieved in practice, not by risk assessment. Therefore, statements requesting that MACT be more stringent due to the risk impacts from ethylene oxide are not appropriate. In addition, the Agency is required to consider MACT for area sources but may elect to require GACT if MACT is unreasonable. Where appropriate, the Agency has considered the health effects of ethylene oxide in conjunction with cost effectiveness. Risk for sources below 1 ton/yr and for aeration room vents at affected area sources greater than 1 ton/yr were calculated by the Agency and were not determined to be significant when considered in conjunction with cost effectiveness. While the Agency appreciates the information submitted by commenters indicating high risk impacts associated with the standards, the EPA is not certain of the methodologies used to calculate the submitted risk information and did not receive sufficient information that supports the commenters' statements regarding risk for each of the emissions points.

The Agency also notes that it is required to focus on the remaining risk from emissions not subject to the NESHAP. After implementation of these NESHAP for the source category, the Agency will examine the residual risk for major sources and area sources subject to MACT for this source category under § 112(f) of the amended Act. The Agency will then promulgate standards if necessary to reduce excessive risks.

2.2.5 Consideration of State and Local Regulations

Comment: Five commenters (10, 16, 17, 18, 19) suggested EPA consider State and local regulations in MACT determinations. One commenter (19) stated that EPA's proposed standards for major and area sources are inadequate because they exempt certain emissions points from control and because the standards for the emissions points that are regulated do not reflect "maximum achievable control technology" as required by the Clean Air Act. The commenter stated that EPA should consider State and local regulations when identifying MACT and the MACT floor. The

commenter added that a consideration of State and local standards would compel EPA to lower applicability levels, increase the stringency of the emissions limits for major and area sources for aeration rooms, sterilizer vents, and to control chamber exhaust vents and other emissions points. This commenter disagrees with EPA's position that standards may not be established without emissions reduction data regardless of State and local regulations.

Several commenters (16, 17 and 19) stated that the best controlled similar sources for ethylene oxide sterilization and fumigation are those facilities in the State of California that are currently meeting the requirements of CARB's ATCM and AQMD's Rule 1405. The commenters suggested that the MACT floor for new and existing sources be revised to reflect a higher destruction efficiency (the commenter submitted a copy of AQMD Rule 1405 and the respective control technologies and emissions cutoffs). One commenter (16) suggested that EPA adopt more stringent levels such as those currently being implemented and enforced in California. The commenter added that this is feasible and cost effective as evidenced by the commenter's experience (the commenter stated that data are available to support this suggestion). One commenter (19) indicated California State and local regulations that require more stringent controls than those required under the proposed regulation. The commenter stated that a review of State and local aeration room vent standards would compel EPA to regulate aeration room emissions from area sources (the commenter noted California State and local regulations). The commenter also referred EPA to SCAQMD for emissions reduction data on chamber exhaust control devices. The commenter recommended that controls be required for chamber exhaust vents at major and area sources because California requires controls of this vent at facilities using more than 600 lb/yr of ethylene oxide. Another commenter (18) stated that because BAAQMD regulations require control of chamber exhaust vents at sources using more than 600 lb/yr of ethylene oxide, the

NESHAP should be revised to include these controls at least for new sources.

One commenter (10) stated that EPA has failed to consider New York's program when determining the MACT standard for ethylene oxide commercial sterilization. The commenter stated that the State of New York maintains a Source Management System (SMS) data base of 79 facilities with ethylene oxide sterilizers; EPA did not evaluate the MACT standard and the 12 percent MACT floor using New York's current data base. The commenter stated that failure to use current data neglects sources located and controls required for ethylene oxide sources in New York in recent years.

Response: The standards for this source category were based on the data available to the Administrator at the time of proposal and on data submitted by commenters after proposal. Section 112(d)(3) of the Act states that MACT emissions limitations are based on the "best performing . . . existing sources . . . for which the Administrator has emissions information." The Agency developed a nationwide commercial sterilization data base that it believes accurately represents commercial ethylene oxide sterilization and fumigation operations on a national basis (commenters submitted additional data regarding control of area source aeration room vents and major source chamber exhaust vents and this information was incorporated into the data base, see Sections 2.2.6 and 2.2.7, respectively). This data base was used in determining MACT floors for the emissions points addressed in the NESHAP and includes information on 13 New York and 19 California commercial ethylene oxide sterilization and fumigation operations. The Agency appreciates notification that a State data base is available.

The EPA did consider State programs in determining these standards. In regard to the emissions reduction required for sources in New York and California, the Agency appreciates the information and believes that it supports the Agency's findings of the level of control at the MACT floor. The statement that

there are 79 facilities with ethylene oxide sterilizers in New York does not necessarily correspond with the Agency's data base because the Agency is uncertain whether this figure represents sterilization units at facilities that are not addressed under these standards (e.g., hospital sterilization facilities). Because the standards in the final rule require the same minimum level of control as the New York State requirements (99 percent emissions control for the sterilization chamber vent, a maximum emissions concentration of 1 ppmv ethylene oxide for the aeration room, and a control requirement or an emissions limit for the chamber exhaust vent), the Agency does not see where its determination of MACT has not considered these facilities. The California control requirements include a 99 or 99.9 percent control efficiency for the sterilization chamber vent depending on the size of the source and a 95 or 99 percent control requirement for the aeration room vent depending on the source size. The Agency has not received sufficient information to demonstrate an emissions reduction of 99.9 percent on a continuous basis. The California regulation also requires combined control of the aeration room vent and the chamber exhaust vent for sources greater than 2.5 tons/yr ethylene oxide usage but does not require source testing to confirm the emissions reduction achieved continuously. The New York and California requirements do apply to commercial ethylene oxide sterilization and fumigation operations using smaller amounts of ethylene oxide, i.e., nonmajor sources, but it is the prerogative of any State to be more stringent than Federal emissions standards.

2.2.6 MACT and GACT Considerations for Aeration Room Vents

Comment: One commenter (18) recommended that sources using at least 20,000 lb/yr [10 tons/yr] of ethylene oxide be required to reduce aeration room vent emissions by 99 percent or to 1 ppmv, whichever is more stringent, and that emissions below the detection limit of the test be considered in compliance. One commenter (17) stated that because the 1 ppmv emissions limit can be circumvented by increasing the air flow through the vent,

sources required to meet the standard should be required to meet a <1 ppmv concentration and 99-percent control requirement, so that the more stringent limit prevails.

One commenter (14) stated that the standard as written would not allow use of one piece of equipment to control both the sterilizer vent and aeration room vent emissions, i.e., if there are simultaneous emissions from both vents, it may not be possible to show that aeration room vent emissions are controlled to less than 1 ppmv. Use of a catalytic oxidizer will give 99 percent control of aeration room vent emissions, which typically are less than 50 ppmv, so that controlled emissions will be under the 1 ppmv limit. However, given that sterilizer vent emissions, which may be several thousand parts per million, are also controlled, total emissions from a combined control system may be greater than 1 ppmv even with overall 99 percent control.

Response: The Agency proposed a 1 ppmv emissions limit for major source aeration room vents because the inlet concentrations from the aeration room vents are typically relatively low and because the outlet concentrations of some of the controlled aeration room vents approach the levels of detection for ethylene oxide and would preclude a demonstration of compliance with an "equivalent" percent reduction standard (i.e., the control device is achieving 99 percent reduction and the outlet concentration is below the detection limit). The commenters' suggestion to require the more stringent limit or reduction for this emissions point is not technically feasible for sources with low ethylene oxide concentration because the outlet may not be detectable.

While the inlet concentration for most aeration room vents alone is typically less than 100 ppmv, the inlet concentration to the control device for some aeration room vents, especially those manifolded with other vents such as the chamber exhaust vent, may be greater than 100 ppmv. If a control device used to control these emissions is operating at 99 percent efficiency, then such a source would not meet the 1 ppmv standard for this emissions point. The final rule therefore provides additional flexibility

for facilities by allowing owners or operators of major sources to control emissions from aeration room vents either to a maximum outlet concentration of 1 ppmv or a 99 percent reduction of the inlet concentration, whichever is less stringent. There has been no change in the level of the standard for major source aeration room vents since proposal; the percent reduction and the concentration limit are equivalent requirements.

Comment: Eleven commenters (03, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19) indicated that control requirements for area sources are not appropriate. One commenter (10) believed that risk should be considered when determining whether to apply MACT or GACT to area sources. Two commenters (16 and 19) suggested that MACT standards be used for new area sources as well as for existing area sources. One of these commenters (16) stated that they have annual source test results to support this recommendation and stated that the availability, feasibility, and cost effectiveness of controls have been demonstrated in the South Coast Air Basin. One commenter (13) stated that the proposed control requirements for area sources (i.e., MACT for existing area sources and GACT for new area sources) [aeration room vents] appear to be applied contrary to the method expected. The commenter added that this leads to the standards for new sources being less stringent than the standards for existing sources, which is the reverse of common practice. The commenter recommended that the same emissions standards be applied to both new and existing area sources. The commenter suggested that MACT be applied to area sources, with less stringent requirements for recordkeeping and reporting than for major sources. One commenter (11) suggested that EPA recalculate the best performing 12 percent MACT floor for area sources.

Four commenters (03, 11, 17, 18) indicated that the regulation for aeration room vents should apply to sources having emissions less than 10 tons/yr. One of these commenters (03) indicated that all facilities should be required to control emissions from the aeration room vent and indicated that some States do require control of this vent. One commenter (15)

suggested that all regulated sources be required to control both aeration and sterilizer exhaust emissions. The commenter stated that such controls have been required in Rhode Island for commercial sterilizers. One commenter (13) suggested that aeration room vent emissions be directed through the sterilizer control device. The commenter stated that the acid-water scrubber should be effective at this low concentration but questioned if catalytic oxidizers would be effective. One commenter (12) constructed an acid-water scrubber for combined control of sterilization chamber and aeration room vents. One commenter (10) indicated that one catalytic oxidizer at a New York facility controls both the sterilizer vents and aerator exhaust.

Another commenter (17) recommended a 1 ton/yr emissions cutoff for regulation of aeration rooms and also indicated that several State and local agencies have adopted this cutoff, proving that such measures are feasible and cost effective. The commenter added that this cut-off would be more protective of public health. This commenter also stated that aeration room vents should be controlled by 95 to 99 percent at new sources using 600 lb/yr [0.3 ton/yr] or more. One commenter (18) recommended that sources using between 600 lb/yr and 5,000 lb/yr [0.3 to 2.5 tons/yr] of ethylene oxide should be required to reduce emissions from the aeration room vent by 95 percent; facilities using more than 5,000 lb/yr [2.5 tons/yr] of ethylene oxide should be required to control aeration room vent emissions by 99 percent.

Two commenters (11, 14) indicated manifolded control for the aeration room vent would be cost-effective. One commenter (11) suggested an emissions cutoff of 5,000 lb/yr [2.5 tons/yr] and indicated that this level has been adopted in several States. This commenter indicated that control of the aeration room vent would be appropriate because one catalytic oxidation unit can control the aeration vent as well as the sterilization chamber vent, and the capital burden to the facility would therefore be minimal. The commenter added that increases in cost would come

in the form of higher operating costs due to the continuous operation of the emissions control equipment. This commenter further stated that if the facility is utilizing heated aeration cells, cost can be further mitigated by reclaiming waste heat for the aeration rooms from the catalytic process. This commenter submitted information on 36 facilities utilizing catalytic oxidation for the control of aeration room emissions to a minimum level of 99 percent reduction. The commenter stated that many of these facilities are below the 20,000 lb/yr [10 tons/yr] ethylene oxide use limit and suggested that EPA correlate emissions levels using their existing data base and reevaluate the aeration room vent MACT floor.

One commenter (14) stated that the total national cost of controlling ethylene oxide emissions would be reduced by the use of manifolded controls for sterilizer and aeration room vents. The commenter stated that the cost of a manifolded control system would be much less than the $600,000 cost estimate made by EPA for separate controls at such a facility. This commenter stated that the proposed standard does not take account of the possibility of using one piece of equipment to control both sterilizer vent and aeration room vent emissions. The commenter added that even though one piece of equipment can control emissions from both points at a lower cost than two separate devices, the standard as written would preclude this alternative which is being offered commercially today. The commenter suggested that the final rule expressly allow the use of manifolded controls in order to provide the opportunity for lower compliance cost and improved cost effectiveness. The commenter stated that such a manifolded device would greatly reduce the costs of control as estimated by EPA in the preamble and background information document.

Response: All sources emitting less than 1 ton/yr of ethylene oxide will continue to be exempt from the emissions limits of this regulation (see Sections 2.1.2 and 2.2.4). For affected area sources, the Administrator stated in the preamble to the proposed rule that if commenters supplied data to indicate

that existing area sources are controlling aeration room vent emissions and that there is a controlled MACT floor, MACT would be rejected and GACT selected based on cost effectiveness, as provided for in § 112(d)(5) of the amended Act. Given that the cost effectiveness is high, rejection of a MACT standard that would require aeration room vent control in favor of a GACT standard with no control would alleviate this cost burden for area sources. The Agency believes that the costs associated with requiring controls on aeration room vents at area sources are prohibitive after consideration of the emissions reduction achieved by such controls.

While the Agency agrees with the commenters regarding the attractiveness of manifolded control devices for some vents, in some cases it may not be possible to manifold an additional emissions vent type. Control devices are typically designed to control a specific vent, such as packed-bed scrubbers for the sterilization chamber vent. The Agency does not believe that combined control for the aeration room vent is feasible at all sources and has not received information demonstrating that the high flow rate and low concentrations typical of aeration room vent emissions may be easily combined with an existing control device. While several of the commenters suggested that combined control for the area source aeration room vents provides lower costs, the EPA does not believe it is appropriate to base its cost estimates on a manifolded system for this vent since this approach may not be an option for all existing sources. In addition, the cost for aeration room vent control includes not only the necessary ducting to a control device if manifolding is feasible but also the cost to construct a new aeration room if the source is not currently controlling these emissions. It has also been suggested by commenters that the aeration room vent emissions be combined with emissions from the chamber exhaust vent, but the MACT floor for chamber exhaust vents at area sources remains at no control (see Section 2.2.7). While the Agency has required control of major source chamber exhaust vents and has received information that emissions from this vent are

commonly combined with emissions from other vents, in general, the only costs for controlling the chamber exhaust vent at major sources are attributable to ducting.

The commenters submitted sufficient data to enable the Agency to reassess the MACT floor for aeration room vents at existing area sources. The MACT floor for existing sources in the final regulation is controlled. However, data received from commenters were not sufficient to allow the Agency to alter its cost-effectiveness calculations associated with controlling emissions from the aeration room vents of existing area sources. Due to this high cost effectiveness, MACT has been rejected and GACT selected for existing aeration room vents in the final rule. The final rule therefore applies GACT to both existing and new area sources and does not require reduction of emissions from aeration room vents. Control of only the sterilization chamber vents (99 percent emissions limitation) is required for area sources.

Comment: One commenter (13) stated that applying GACT rather than MACT may exempt new area sources from operating permit requirements. The commenter stated that if GACT is chosen for new area sources, it should be applied to existing area sources also, to avoid the confusion of some sources in a category being exempt from operating permits on the basis of their construction date. If MACT is chosen then both existing and new area sources could be covered by a model "General Permit," which would streamline the paperwork to obtain an operating permit, along with a 5-year extension of operating permit requirements.

One commenter (18) recommended that EPA exempt area source sterilizers from Title V permits because limited benefits would be expected from the periodic review of these permits for this source category. The commenter added that in the event EPA chooses to regulate sterilizers using less than 1 ton/yr, Title V permits should not be required.

Response: Regarding the application of the Title V operating permit program to area sources, the final rule for the

operating permit program promulgated on July 21, 1992 (57 FR 32250) states that "... any other source, including an area source, subject to a hazardous air pollutant standards under section 112..." is an affected source required to comply with the Part 70 operating permit requirements. The final rule later specifies that the Part 70 permitting program will be used to implement standards for area sources developed using GACT. The Agency therefore believes that no confusion will result from regulation of area sources with either MACT or GACT. In regard to the commenter's request for an extension of the permit requirements, the Agency believes that the 5 year extension for nonmajor sources contained in Title V would be appropriate.

Comment: Four commenters (10, 13, 18, 19) expressed concern regarding the role of § 112(f) in determining the applicability of MACT or GACT to area sources. One commenter (18) stated that area sources should be regulated under MACT because such sources should be subject to later review under § 112(f). Another commenter (13) stated that avoiding the application of § 112(f) (residual risk analysis) should not be a factor in deciding to exempt area sources from MACT because smaller sources can often pose a high risk, especially with a pollutant like ethylene oxide. One commenter (10) stated that § 112(f) should be considered when deciding whether to select MACT or GACT for an area source category. Another commenter (19) also suggested that the residual risk analysis requirements of § 112(f) should be considered when determining whether MACT or GACT should apply to area sources when they asserted that the setting of GACT standards for area sources would weaken protection from ethylene oxide exposure and would remove these sources from consideration under the residual risk analysis required by § 112(f).

Response: The Agency is required to examine the residual risk under § 112(f) of the Act for major sources and for area sources regulated by MACT. The Agency has not attempted to avoid the requirements of § 112(f) in its determinations to apply GACT to area source aeration room vents in this source category, as one commenter suggests. While the Agency is required to examine

area sources regulated by MACT, the Agency notes that it may also choose to examine the residual risk for area sources subject to GACT as well. Therefore, area sources subject to GACT may be included in the residual risk study and § 112(f) standards may be promulgated for these area sources as well as for those subject to MACT.

2.2.7 MACT for Chamber Exhaust Vents

Comment: Nine commenters (03, 06b, 10, 11, 13, 14, 17, 18, 19) suggested controlling emissions from the chamber exhaust vent. One commenter (17) stated that they were aware of facilities that are required to vent the emissions from the chamber exhaust vents to the control device. One commenter (13) suggested that emissions from the chamber exhaust should be controlled at major sources because of the risks posed by the amount of ethylene oxide uncontrolled from this vent. The commenter suggested that a lower concentration of about 1,000 ppmv be considered for the chamber exhaust vent standards. A commenter (19) referred EPA to SCAQMD for emissions reduction data on chamber exhaust control devices. The commenter recommended that controls be required for chamber exhaust vents at major and area sources because California requires controls of this vent at facilities using more than 600 lb/yr of ethylene oxide. Another commenter (18) stated that because BAAQMD regulations require control of chamber exhaust vents at sources using more than 600 lb/yr of ethylene oxide, the NESHAP should be revised to include these controls at least for new sources. A commenter (03) indicated that the Puget Sound has facilities that control emissions when the sterilization chamber door is opened and including small sources where chamber exhaust vents are routed to the control device. One commenter (06b) stated that they already have two catalytic oxidizers in place that utilize the combined feed of aeration and sterilizer vacuum pump [chamber exhaust vent] flows and that combining sterilizer exhaust and aeration exhaust reduces the use of clean-burning natural gas, a nonrenewable energy source. One commenter (10) stated that the chamber exhaust and the aerator exhaust, which are similar in

nature, could be vented to a single control device. This commenter stated that chamber exhaust vent emissions could be combined with aeration exhaust and routed to a single control device even though they are unaware of a facility so-controlled. One commenter (15) suggested that all regulated sources be required to control both aeration and sterilizer exhaust emissions. The commenter stated that such controls have been required in Rhode Island for commercial sterilizers.

One commenter (14) noted that relatively inexpensive control of chamber exhaust vent ethylene oxide emissions should be possible through the use of a single piece of equipment to control the emissions from multiple points. The commenter suggested that the chamber exhaust vent could be manifolded to the control device used to control either sterilization chamber or aeration room vent emissions; use of such systems should provide additional emissions reductions for small marginal increase in total costs and thus with reasonable cost effectiveness. The commenter suggested that EPA reconsider its rejection of regulatory alternative A, which required 99 percent reductions in chamber exhaust vent emissions at major sources.

One commenter (11) supplied information on 32 systems where emissions from the chamber exhaust or door hood were controlled to a minimum level of 99 percent. The commenter suggested that the MACT floor requirements be changed for both major and area sources to control sterilizer chamber exhaust vents to a level of 99 percent by either directing the emissions to the control device or by introducing further cycle/process changes to reduce the in-chamber concentration to below 5,300 ppmv by conducting further sterilizer evacuations which would be controlled by the sterilizer vent emissions control device. This commenter requested that the emissions cutoff for regulation of exhaust chamber vents be lowered to 5,000 lb/yr [2.5 tons/yr]. Another commenter (10) stated that the MACT standard for chamber exhaust vents should include the number of air washes, including the vacuum, residence time, and temperature associated with these air washes, required prior to opening the sterilizer chamber door.

Response: The Agency agrees with the commenters regarding the attractiveness of manifolded control devices for controlling ethylene oxide emissions for some emissions points. The Agency appreciates the commenter's submittal of data indicating that manifolding is practiced for the chamber exhaust vent. The data were sufficient in detail to allow a reassessment of the MACT floor for the chamber exhaust vent at major sources. At least six chamber exhaust vents at major sources are controlled by manifolding the vent to the aeration room vent or sterilization chamber vent control device when a catalytic oxidizer is used. The Agency contacted the commenter for additional information and has incorporated the data into the commercial sterilization data base. The MACT floor for major source chamber exhaust vents in the final regulation is control by ducting this vent to a control device for the sterilization chamber or aeration room vent or venting to a dedicated control device achieving 99 percent emissions reduction. A specific manifolding or venting scenario for control of this vent has not been specified because the Agency believes that the owners or operators of a particular source are best able to determine the most efficient way to comply with the standards.

The MACT floor for area source chamber exhaust vents remains unchanged since proposal at no control. While the level of the standard at area sources has not changed, an addition has been made to the requirements to provide flexibility to facilities. Area sources may comply with the ethylene oxide concentration limit as was proposed or may comply with a 99 percent emissions reduction for chamber exhaust vent emissions that are vented to a control device (either manifolded to a control device for sterilization chamber vent emissions or vented to a dedicated control device).

The Agency is providing additional flexibility to sources in demonstrating compliance with the standards in the final rule and has included language that provides alternative monitoring requirements and compliance provisions for controlled chamber exhaust vents and aeration room vents. The Agency has provided a

mechanism for sources choosing to manifold vents or vent types to demonstrate compliance with the standards but believes that one approach should not be endorsed or preferenced over another. The final rule allows a source to demonstrate compliance for either the chamber exhaust vent or aeration room vent through parametric monitoring of the performance of a control device. Whether the control device is manifolded to other vents or vent types is immaterial to the compliance demonstration, provided that the conditions for demonstrating compliance are met.

2.3 COMPLIANCE DATES

Comment: Three commenters (04, 05, 12) suggested the compliance date should be 3 years after the effective date; one commenter (04) indicated that a compliance date of 3 years was originally stated in the draft proposed rule available on the EPA Technology Transfer Network. Two of these commenters (04, 05) stated that 2 years would not be enough time for many companies to complete material and process evaluations and to obtain regulatory approval associated with investigating and converting to alternative sterilization methodologies. Another of these commenters (12) indicated that 2 years would not be enough time to: (1) design a system for the aeration cells that will comply fully with the new standard, (2) obtain bids, (3) build the necessary control equipment and associated auxiliary systems, (4) install the system in such a way that it minimizes down time, and (5) start up and debug the system. This commenter provided the following schedule: (1) research available technology and systems--6 to 8 months; (2) prepare and submit permitting requirements--3 months; (3) receive approval for construction permit from the State--8 months; and (4) order systems, complete facility modifications, installation, and debugging the system--12 to 15 months. This schedule indicated a total of 29 to 34 months for completion.

One commenter (19) stated that the compliance date should be shortened to 1 year after the effective date. The commenter stated that industry has been provided a great deal of notice that emissions would be regulated, and that industry

representatives indicated during hearings for the California regulation development that controls would be operable within 1 year.

Response: The Agency agrees with several of the commenters that the compliance time frame for ethylene oxide commercial sterilization and fumigation facilities should be extended. The EPA recognizes that some of the facilities within the source category will have to investigate and install control devices at their facility to meet the standards. Also, some sources may wish to investigate alternative sterilization methods. Based on reasons presented by some of the commenters, EPA has extended the compliance date to 3 years after the promulgation date for all sources subject to this rule. The extension of the compliance date is appropriate and should not result in adverse effects on the environment because several large emitters, i.e., major sources, are already well-controlled. At the same time, the extension provides smaller, less well-controlled sources additional time to achieve compliance. The EPA believes that the 3 year timeframe will address these commenters' concerns and still ensure implementation of controls in a timely fashion. New sources with startup after the 3 year compliance date will be required to comply with the emissions standards upon startup of the source.

2.4 MONITORING REQUIREMENTS

2.4.1 Initial Performance Testing

Comment: One commenter (18) stated that the conditions during the initial compliance test for the sterilization chamber vent do not reflect standard operating conditions; this presents problems for both of the referenced control technologies.

Two commenters (17 and 18) stated that EPA should reconsider the determination of a temperature baseline for catalytic oxidizers because there will be significant differences in the temperature responses exhibited during the compliance tests (run on an empty chamber) and actual operation with material present in the sterilization chamber. The commenters recommended that EPA review actual source test data for a variety of different

sterilizers, running with no load and with a full load, to determine the impact these variables are likely to have.

Response: The Agency believes that the conditions specified during the initial compliance test primarily affect the concentration of ethylene oxide being delivered to the control device. Although the concentration of ethylene oxide may be different from standard operating conditions, the differing amount is not expected to preclude the control device from meeting the standard. The conditions for the initial test (i.e., empty chamber) were specified to eliminate interference from product retention of ethylene oxide.

For sterilization chamber vent emissions controlled with oxidation units, two initial compliance tests will be performed on the sterilization chamber vent: one during the first evacuation of the sterilizer chamber to demonstrate that the control device is designed properly and one during the last evacuation to establish the appropriate baseline temperature. During the compliance test for the first evacuation, the owner or operator should deliver the same mass of ethylene oxide to the chamber as would be used for typical operation. Demonstration of the baseline temperature during the last evacuation addresses concerns that a baseline temperature established during the first evacuation would not be sustainable for subsequent evacuations where the ethylene oxide concentration is lower. For an oxidation unit, the temperature will not elevate as significantly with the lower concentration in the last evacuation, and an appropriate baseline temperature will be determined. Because an additional compliance test has been added at the final evacuation where inlet concentration is lower, the final regulation permits sources to demonstrate compliance with the standard during the performance test for the last evacuation if the outlet concentration is below the detection level of ethylene oxide when the inlet concentration is approximately 50 ppmv or lower; the source must be able to demonstrate the inlet concentration.

The initial compliance test for the chamber exhaust vent will be performed with procedures similar to those used for the

performance during the last evacuation of the sterilization chamber. Use of a low ethylene oxide concentration that allows demonstration of the emissions reduction achieved during the performance test will provide a baseline temperature applicable to all chamber exhaust vent cycles. As explained above for the last evacuation for the sterilization chamber, the final regulation permits the source to demonstrate compliance with the standard if the outlet concentration is below the detection limit for ethylene oxide and the inlet concentration is approximately 50 ppmv or lower.

The Agency believes that the revised monitoring requirements in the final rule are not adversely affected by the conditions during the initial compliance test and that these conditions enable correct measurement of the emissions reduction achieved by the control devices and the setting of monitoring parameters to assure future compliance with the standards.

Comment: One commenter (18) stated that requiring the ethylene glycol solution to be maintained at the average concentration recorded during the initial source test is unreasonable and may present practical difficulties for the source. The commenter stated that because sources could perform at a level substantially above the required 99 percent control during the initial test, the actual performance could fall off by as much as two orders of magnitude before the source would be controlled to less than 99 percent, but if parametric monitoring showed departure from the established baseline, the source could be found in violation. The commenter recommended that the baseline for the parameters be set when the source is operating at the compliance level or an appropriate range should be established.

Two commenters (03, 17) stated that the proposed compliance determination and monitoring requirements for acid-water scrubbers would require a facility to determine the maximum concentration of ethylene glycol in the scrubber liquor under a "worst-case" situation. One commenter (17) stated that the sterilization chamber vent monitoring requirements for acid-water

scrubbers may not be appropriate because the baseline established during the initial performance test may be derived when the source is achieving greater control efficiency than is required under the standards. The commenter added that as the equipment ages, a degradation of the control may be experienced such that the monitored parameter may show noncompliance with the standard when in fact, the source is still in compliance. The commenter requested that if parametric monitoring was to be implemented for these controls, the baseline must correspond to the required level of control, not a higher level.

Two commenters (11 and 16) suggested that annual performance testing be required (in addition to the initial performance test) as part of the monitoring requirements for the standards. One commenter (19) stated that the final rule should include more frequent performance testing of control equipment to prevent deterioration of the control equipment.

Response: The Agency has incorporated monitoring requirements into the proposed and final regulations that provide a continuous determination of compliance with the standards. The underlying principles for these monitoring requirements are that the parameters monitored (where parametric monitoring is used) are to be a direct indicator of compliance. Under the final rule, limits for monitored parameters will first be established during an initial performance test and will be monitored thereafter. In the interest of reducing the costs to affected facilities, additional (e.g., annual) compliance tests are not required under the final rule. The Agency believes that an initial performance test of the control device is sufficient to establish the monitoring parameters needed for determining continuous compliance. However, the Agency offers the flexibility to a source to perform additional performance tests and reestablish new limits for monitored parameters at any time. The Agency believes that this flexibility will address the commenter's concerns about a source showing noncompliance with a higher emissions limit than is contained in the standard when the source is in compliance with the actual standard.

The final rule does not require that the ethylene glycol concentration be maintained at an average concentration established during the initial performance test. The ethylene glycol concentration established during the initial compliance test is a concentration not to be exceeded by the source. In determining the monitoring parameters for the acid-water scrubber, it would be advantageous for the owner or operator to do the initial performance test at the end of the liquor cycle when the ethylene glycol concentration is at the highest point that still provides a 99 percent reduction for the acid-water scrubber. Because the baseline parameter has been changed from an average value (e.g., maintain ethylene glycol concentration at the average baseline concentration) to a maximum or minimum value (e.g., maintain temperature below the minimum oxidation temperature), it is not necessary to specify appropriate ranges for these parameters as one commenter suggested.

2.4.2 Monitoring for Acid-Water Scrubbers

Comment: Eight commenters (03, 04, 05, 06a, 06b, 13, 17, 18) provided comments on the monitoring requirements for acid-water scrubbers. Several commenters (04, 05, 06b, 17, 18) stated that continuously measuring ethylene glycol concentration is not feasible, practicable, or necessary. Two commenters (03, 17) stated that the proposed compliance determination and monitoring requirements for acid-water scrubbers would require a facility to determine the maximum concentration of ethylene glycol in the scrubber liquor under a "worst-case" situation. One commenter (17) stated that ethylene glycol monitoring is not the best parameter to monitor to assure compliance with the sterilizer vent standards and that EPA should select a parameter other than ethylene glycol concentration or offer other parameters as alternatives. The commenter suggested that acid concentration is much easier to measure than ethylene glycol concentration and would be a better surrogate for scrubber performance.

One commenter (04) stated that acid-water control units operate on a batch basis with glycol concentration starting near

zero at the beginning of an operating cycle and increasing up to a predetermined maximum, at which time the glycol is removed and neutralized. The commenter added that makeup water is added, pH adjusted, and a new cycle begins. The commenter stated that enough acid is added at the beginning of each cycle to maintain the proper pH through the complete cycle. One commenter (13) stated that the proposed monitoring requirements for acid-water scrubbers (i.e., continuous monitoring of the scrubber liquor ethylene glycol concentration) for sterilization chamber vents seems excessive since the time between changes of the liquor is often several months. The commenter suggested the initial use of frequent monitoring to determine the rate at which the concentration increases in the liquor, followed by less frequent monitoring, especially if the maximum content of ethylene glycol is set safely below the level required to attain the desired level of efficiency. One commenter (05) stated that their facilities typically operate 3.5 months before approaching the manufacturers recommended ethylene glycol concentration limit. One commenter (06b) stated that a new batch of scrubber liquor requires a physical check of the system parameters and that only the ethylene glycol concentration would change gradually and predictably over the time that the batch fills the storage tanks; continuous or even hourly monitoring of glycol concentration would therefore not be needed. The commenter stated that facilities having typical scrubber units would not see changes in the ethylene glycol concentration of even 0.5 percent by weight per day of sterilization. The commenter added that to detect such relatively small changes in glycol concentration would require specific onsite gas chromatographic analysis that would cost over $15,000 and require special instrument training of hourly employees.

Two commenters (04, 05) stated that they knew of no means to continuously monitor acidified ethylene glycol concentration. One commenter (06a) questioned the ability of available technology to continuously monitor the ethylene glycol concentration in the scrubber liquor due to the sample matrix,

which is very acidic and contains other dihydric glycols which can interfere with accurate determinations of ethylene glycol. This commenter indicated that periodic determinations are achievable, providing adequate sample preparations are carried out in a laboratory.

Several commenters (03, 04, 05, 06b, 13, 17, 18) suggested alternate or modified monitoring requirements for acid-water scrubbers. The following alternatives were suggested:

1. Establish a maximum limit on the amount of ethylene oxide used or scrubbed (03, 17, 18), after which the scrubbing liquor must be changed (17);

2. Measure pH (17, 18) periodically or prior to scrubbing a batch of ethylene oxide (18);

3. Measure ethylene glycol concentration (05, 06b, 13) at the end of each week of operation (05) or less than continuously (06b, 13);

4. Monitor the level of the scrubbing liquid in the tank (17, 18) and establish a maximum tank level that correlates to an ethylene glycol concentration after which the liquor must be changed (17); and

5. Monitor all of the following: monitor gas flow rate or tower pressure differential, the liquid flow rate (or liquid height for reaction/detoxification units), and the liquid temperature; measure pH at the start and end of each operating cycle; and measure the ethylene glycol concentration at the end of each operating cycle (04).

One commenter (18) recommended that if ethylene glycol concentration is to be used as a surrogate parameter for scrubber efficiency, an acceptable range be established, based on a correlation between ethylene glycol concentration and scrubber performance. One commenter (03) indicated that monitoring the ethylene oxide usage would be a much easier method for sources and the regulatory community to implement. One commenter (04) stated that their recommendations for monitoring parameters provide more effective process control and assurance of compliance. The commenter also suggested that maximum or minimum

values for each parameter would be established based on manufacturers' recommended limits and verified during initial compliance testing.

Response: The Agency agrees with the commenters that the continuous monitoring requirements proposed for acid-water scrubbers are not necessarily appropriate. The Agency has carefully considered each of the suggested alternative monitoring scenarios submitted by the commenters.

One alternative monitoring parameter suggested by the commenters is tracking of ethylene oxide usage. The owner or operator would correlate the maximum ethylene oxide usage to the maximum ethylene glycol concentration that still provides a 99 percent emissions reduction for the scrubber. Implementing use of this parameter would require: (1) accurate recordkeeping of all ethylene oxide purchases and use, (2) determination of the ethylene oxide emissions split for each emissions point vented to the control device, and (3) determination of ethylene oxide retention properties for each product sterilized. The Agency does not believe this monitoring approach is appropriate due to uncertainty and variability associated with both the emissions split for each vent and the ethylene oxide retention rates of ethylene oxide for products sterilized. Tracking of ethylene oxide usage has not been included in the final regulation as a referenced monitoring parameter.

Several commenters suggested pH as an appropriate monitoring parameter for acid-water scrubbers. Monitoring the pH of the scrubber liquor is not technically feasible because the pH change over the life of the liquor cycle is typically not measurable. Because the Agency has not received sufficient data indicating that pH monitoring is an acceptable parameter for demonstrating continuous compliance, the Agency has not included pH monitoring as a referenced monitoring parameter in the final rule.

Continuous monitoring of ethylene glycol concentration to determine compliance has been refuted by commenters based on the small incremental changes in ethylene glycol concentration expected over the liquor cycle and the cost of analysis equipment

and employee training and time for performing the analysis on a continuous basis. The Agency has determined through contact with vendors and industry that ethylene glycol concentration is commonly used for compliance determination but agrees that continuous monitoring of ethylene glycol concentration is not necessary. Monitoring of the ethylene glycol concentration demonstrates that ethylene oxide from the vent outlets is being removed and converted to ethylene glycol in the scrubber liquor. Based on the slow change in concentration, the final rule requires monitoring of the ethylene glycol concentration once per week. With less frequent monitoring, it is possible for an affected source to sample the liquor and send to a laboratory offsite for analysis to avoid the cost for analysis equipment.

Monitoring of the scrubber liquor level in the tank was also suggested by commenters as an alternative parameter to monitor. The owner or operator would correlate the maximum level of liquor allowed in the tank to a maximum ethylene glycol concentration that still provides a control efficiency of 99 percent for the scrubber. The increase in mass (until total solution is 40 to 60 percent ethylene glycol by weight) and therefore volume in the scrubber liquor storage tank demonstrates that ethylene oxide from the vents is being scrubbed and converted to ethylene glycol in the scrubber liquor. The owner or operator must place liquid level indicators on the liquor storage tank; minimal employee time and training is necessary for monitoring the liquor level in the tank. [This parameter may be used for monitoring systems that continuously collect the liquor (i.e., a batch operation) and purge the system only at the end of the cycle. While the EPA does not believe that common practice for scrubber systems in this source category includes periodic purging of the liquor cycle, systems that do not follow a batch process will not be permitted to use this monitoring parameter.]

Monitoring of the operating parameters (i.e., liquid to gas flow rate ratio and temperature) of the scrubber in addition to beginning and end of cycle pH monitoring and end of cycle ethylene glycol concentration monitoring was suggested by

commenters. As discussed above, the Agency does not believe pH monitoring for the system is technically feasible for this source category, and ethylene glycol monitoring demonstrates that the scrubber system is absorbing ethylene oxide from the inlet gas stream. While the EPA agrees that monitoring operating parameters may add some benefit, the EPA is reluctant to require these parameters as referenced monitoring parameters in the final regulation because the Agency has not received data indicating that the monitoring of these additional parameters contributes to the continuous compliance indication as determined by ethylene glycol monitoring. The EPA believes that ethylene glycol monitoring provides a sufficient demonstration of compliance.

The Agency has subsequently revised the referenced monitoring parameters in the final rule to require either: (1) weekly monitoring of the ethylene glycol concentration in the scrubber liquor, or (2) weekly monitoring of the level of liquor in the scrubber liquor tank. Operating the scrubber with a monitored ethylene glycol concentration above the maximum concentration determined during an initial performance test is a violation of the applicable standard. Operation of the scrubber with a liquor level in the tank above the maximum as determined during an initial performance test is a violation of the applicable standard. The Agency believes that these monitoring alternatives provide an adequate measure of compliance while providing reduced burden to owners and operators of the affected sources. A source may choose an alternative to the monitoring parameters referenced in the final regulation if the alternative monitoring parameter is approved by the regulating Agency, as provided for in § 63.8 of the General Provisions. (See Section 2.4.1 for determining monitoring parameters at "worst-case" operation.)

2.4.3 Monitoring for Catalytic Oxidizers

Comment: Six commenters (04, 06b, 11, 13, 17, 18) suggested modifications to the monitoring requirements for catalytic oxidizers. Several commenters (13, 17, 18) stated that the control of the catalyst bed temperature to ±10°F may not be

practicable. One commenter (13) stated that maintenance of such a temperature range is feasible under steady state conditions but would be difficult under the continuously varying concentrations encountered in the evacuation process for the sterilization vent. This commenter suggested the use of a continuous temperature control monitor and recorder on both the inlet and outlet of the oxidizer. The commenter stated that compliance would be shown by having the inlet temperature above a minimum and the outlet temperature below a maximum; both temperatures would be determined during a compliance test when 99 percent efficiency was achieved.

One commenter (04) suggested that the current requirement of ±10°F be deleted and replaced with manufacturers' recommended maximum/minimum temperatures. The commenter stated that catalytic oxidation units used to control chamber vents would operate at widely varying temperatures, depending on the amount of ethylene oxide in the feed stream(s), and that various field tests on one manufacturer's units have demonstrated 99 percent removal efficiencies as long as the catalyst bed temperature is 280°F or higher. Another commenter (11) stated that it is well proven that catalytic units will work as designed if a minimum operation temperature is maintained for the particular catalyst. This commenter stated that compliance with the standards would be shown by having the catalyst bed temperature fall above a minimum operating temperature ±10°F established during a performance test and below a maximum temperature limit established by the manufacturer of the control device. The commenter added that the upper baseline temperature could change with different feed rates, environmental conditions, and air flows and suggested that this upper limit be set on a baseline standard cycle. The commenter suggested that a temperature variation in excess of 50°F from this monitored temperature would constitute a violation of the standards. Both commenters (04 and 11) suggested that monitoring the catalyst bed temperature coupled with periodic efficiency tests (minimum annually) should be utilized for monitoring compliance.

Another commenter (06b) stated that the control efficiency of catalytic oxidation units is dependent on catalyst temperature. This commenter stated that any catalyst used in catalytic oxidizers has been tested in the lab and in the field to show a reliable profile of temperature versus control efficiency. The commenter added that all methods of oxidizing ethylene oxide in air are more effective when the oxidation temperature is higher and that the limitation of ±10°F from the baseline temperature is unrealistic and penalizes those that operate their equipment with a high knowledge of their control efficiency. The commenter stated that this temperature requirement would disallow the use of ethylene oxide control from the sterilizer vacuum pumps [chamber exhaust vent] to be combined with aeration feed to a catalytic oxidizer. The commenter stated that only catalytic oxidizers controlling emissions from sterilizer vacuum pump exhausts would show marked temperature changes and that these changes would always be greater than the proposed 10°F limitation. The commenter added that they already have two catalytic oxidizers in place that utilize the combined feed of aeration and sterilizer vacuum pump [chamber exhaust vent] flows and that combining sterilizer exhaust and aeration exhaust reduces the use of clean-burning natural gas, a nonrenewable energy source. This commenter noted that in the "aeration only" feed streams of ethylene oxide, there is seldom any temperature rise of even 10°F for any new hot aeration/degassing cycles started because the total feed concentrations to the oxidizer are typically 40 parts per million or less. The commenter stated that all aeration cycles show a higher concentration of ethylene oxide degassing early in the cycle (although not necessarily at the beginning of the aeration cycle), usually declining asymptotically with the heated aeration. Two commenters (04, 11) stated that aeration room compliance for catalytic oxidation systems should be determined by continuously monitoring the lower operational temperature limit for the catalyst bed coupled with periodic efficiency tests (minimum annually).

One commenter (13) stated that calibration of the temperature controller to ±10°F is acceptable but seems difficult under § 63.363(b)(2)(ii), where a source is required to control the temperature of an oxidizer chamber under operating conditions to ±10°F using a temperature monitor accurate to ±10°F. Two commenters (17 and 18) stated that the temperature probe required in §§ 63.363(b)(1)(ii) and (2)(ii) should at least be accurate to within 1°F because, as written, any measurement that is at or below the limit of accuracy would be considered a violation.

One commenter (06b) stated that except for major concentrations of ethylene oxide (above 2,000 parts per million) or of cases where the allowable high temperature limits were exceeded, the catalyst will deactivate slowly over a period of years. The commenter stated that this deactivation is fairly reliable and predictable over the long-term, which is shown by performing the annual source test on all catalytic units. One commenter (11) submitted life data from two systems from major sources showing that the performance of the catalyst after one and 2 years has not changed from the original compliance test. The commenter also referred to life test data previously submitted to EPA performed on a catalytic system. The commenter noted that the catalyst in this system operated for 8 years before the catalyst performance fell below 99 percent destruction and the catalyst was then replaced. The commenter noted that this proved that the catalyst will not fail catastrophically and that catalyst life doesn't dramatically change over long periods of time.

Response: The Agency agrees with the commenters that the monitoring requirements for catalytic oxidizers may not be appropriate; the baseline temperature limit of ±10°F is not practicable in all situations. The Agency has considered the alternatives suggested. The commenters suggested that a more accurate measure of compliance would be a requirement that the temperature remain above a minimum oxidation temperature. The Agency has included compliance provisions in the final rule requiring that the oxidation temperature be above a minimum

baseline temperature determined during an initial performance test for the sterilization chamber vent, the aeration room vent, and the chamber exhaust vent. The Agency has not included a maximum temperature as part of the monitoring requirements as some commenters suggested because temperatures above the minimum temperature do not adversely affect performance of the oxidizer unit.

For the sterilization chamber vent, the final rule requires owners or operators of affected sources to: (1) monitor the oxidation temperature continuously, (2) calculate an average oxidation temperature over each cycle (the length of the cycle is based on the cycle length during the performance test), and (3) calculate a three-cycle average every third cycle; an average monitored oxidation temperature more than 5.6°C (10°F) below the baseline temperature established during the initial performance test at a time when the control device achieves a 99 percent emissions reduction is a violation. Similar requirements have been added to the monitoring requirements for sources that vent chamber exhaust vent emissions to a control device.

For aeration room vents controlled with catalytic oxidizers, the Agency agrees that additional flexibility regarding the monitoring requirements is warranted. The final rule requires owners or operators at major sources to monitor either: (1) the concentration of ethylene oxide emissions from the aeration room vent outlet, or (2) the oxidation temperature. For major aeration room vent sources monitoring the ethylene oxide concentration, the owner or operator will: (1) measure the concentration once per hour, and (2) calculate a 3-hour average every third hour. A 3-hour average ethylene oxide concentration greater than 1 ppmv is a violation of the standard. For major aeration room vent sources monitoring the oxidation temperature, the owner or operator will: (1) monitor the oxidation temperature continuously, (2) calculate an average oxidation temperature over each hour, and (3) calculate a 3-hour average every third hour. An average monitored oxidation temperature more than 10°F below the baseline temperature established during

an initial performance test at a time when the control device achieves either a 99 percent emissions reduction or a maximum outlet ethylene oxide concentration of 1 ppmv or less is a violation of the standard. The purpose of the monitoring requirements is to show "continuous" compliance with the standards, and since these monitoring requirements have been developed with this purpose, there would be no reason to require annual compliance testing. An affected source may perform compliance tests other than the initial compliance tests required by the final rule (see Section 2.4.1).

The Agency agrees with the commenters' concerns regarding the accuracy of the temperature probe used to measure the oxidation temperature. The final rule requires that the temperature probe have the same accuracy (±10°F) but requires the oxidation temperature to be above a minimum temperature established during a performance test (i.e., if the monitored temperature falls below this level, a violation of the applicable standard has occurred).

Comment: One commenter (18) stated that the language of 63.363(b)(2)(ii) (determination of violation for catalytic oxidation) should be clarified to specify that compliance is based on the average temperature.

Response: Section 63.365(f) in the final rule details the method for determining the baseline temperature for oxidizer units. The baseline temperature is determined by averaging temperature readings from three test runs. Monitoring will consist of continuous temperature measurement to be averaged over a period of time (i.e., cycles or hours). Depending on the vent type, the source will then calculate an average over the last three cycles or hours. A monitored temperature average more than 10°F below the baseline temperature is a violation of the standard.

Comment: One commenter (14) suggested semiannual calibration of temperature monitor accuracy for sources using catalytic oxidizers given the relative stability of the thermocouples used. The commenter added that failure of

thermocouple monitors tends to be catastrophic, with results that are immediately obvious to facility owners or operators.

Response: The Agency is aware of the reliability of thermocouples; thus, revised guidance on the calibration and maintenance of thermocouples have been added. The final rule requires semiannual calibration of temperature monitors.

2.4.4 Monitoring for Other Control Equipment

Comment: One commenter (04) recommended that monitoring of thermal oxidizers consist of continuous monitoring of fuel gas pressure, pilot flame presence, combustion air flow, and system temperature.

Response: The Agency has included thermal oxidizers as a referenced control technology in the final rule and has therefore incorporated compliance provisions, monitoring requirements, and recordkeeping and reporting requirements for thermal oxidizers. While the Agency agrees that monitoring of each of the mentioned parameters indicates flame stability, the Enhanced Monitoring Reference Document, September 1993, suggests that the outlet oxidation temperature be monitored. Other NESHAP have also incorporated this monitoring requirement for thermal oxidation units, such as the HON. The Agency believes that monitoring of this temperature parameter is sufficient to indicate continuous compliance for this control device. The compliance provisions for thermal oxidizers are as follows: during three performance test runs when the control device meets the applicable standard, the owner or operator shall establish as an operating parameter a baseline temperature averaged over the three runs; thereafter, operation of the sterilizer with the average oxidation temperature more than 10°F below this baseline temperature shall constitute noncompliance with the standard.

2.4.5 Monitoring Requirements for Sterilization Chamber Vents

Comment: One commenter (19) stated that actual measurement of inlet and outlet concentrations of ethylene oxide for the sterilization chamber vents should be required to demonstrate compliance with the percent reduction requirements.

Response: Direct monitoring of the inlet and outlet concentrations would require installation of an online gas chromatograph system and the appropriate personnel and training for operation of the analysis equipment; the Agency believes that this monitoring option is costly for this source category. The Agency believes that the parametric monitoring requirements contained in the final rule are sufficient to demonstrate compliance with the standards. The monitoring requirements were revised in response to comments received from control device vendors, industry, and State and local environmental regulatory agencies and incorporate monitoring provisions as required by the amended Act.

2.4.6 Monitoring Requirements for Chamber Exhaust Vents

Comment: One commenter (04) suggested that facilities that send chamber exhaust vent discharge to a control device be exempt from the monitoring requirements proposed for chamber exhaust vents. The commenter added that monitoring of the control device under these conditions should assure compliance with the standards.

Several commenters (04, 05, 11, 17, 18) suggested that facilities discharging chamber exhaust vents to the atmosphere should have the option of demonstrating end-of-cycle chamber concentrations of less than 5,300 ppmv by using specific validated cycle parameters and controlling additional cycles with the sterilization chamber vent control device. One commenter (04) suggested that this validation of cycle parameters include key process parameters affecting ethylene oxide removal from the vessel (initial concentration, number and depth of air washes), coupled with actual measurement of chamber concentration for representative cycles. This commenter suggested that compliance could be assured through the initial validation and review of sterilization cycle charts which are part of the permanent batch record. Another commenter (05) stated that bringing of the sterilization chamber to one atmosphere and holding it there while sampling the chamber ethylene oxide concentration before activating the fan would allow ethylene oxide to diffuse from the

chamber and increase employee exposures. This commenter added that multiple chambers cycling in close succession would compound this problem. The commenter suggested validating the operating parameters during the initial performance test and following these parameters as part of the monitoring for the chamber exhaust standard.

Response: The Agency agrees with the commenters' that additional flexibility should be provided to owners or operators of area and major source commercial ethylene oxide sterilization and fumigation operations regarding the demonstration of compliance with the chamber exhaust standards. The final rule contains provisions for the owner or operator of major and area affected sources to demonstrate compliance with the applicable chamber exhaust standards. Major source facilities, which are required to control emissions from the chamber exhaust, must demonstrate compliance by monitoring parameters established during a performance test for the control device that is used to control emissions. Area source facilities must monitor the ethylene oxide concentration in the sterilization chamber prior to operation of the chamber exhaust or may choose to control emissions from the chamber exhaust vent and demonstrate compliance by monitoring parameters established during a performance test for the control device that is used to control these emissions. In general, the monitoring requirements and compliance provisions for devices controlling emissions from the chamber exhaust vents are similar to the monitoring requirements and compliance provisions for devices controlling emissions from sterilization chamber vents.

2.4.7 Monitoring Requirements for Aeration Room Vents

Comment: Seven commenters (04, 05, 06a, 09, 11, 17, 18) provided comments on the monitoring requirements for aeration room vents. Several commenters (04, 05, 06a, and 11) stated that the proposed monitoring requirements for aeration room vents at major sources are unobtainable given that the industry-accepted detection limit for ethylene oxide is 0.5 ppmv based on laboratory quality equipment not used continuously. The

commenters also expressed concern that ethylene oxide monitoring would be inaccurate due to the heated sample stream, moisture present in sample lines, and the presence of other hydrocarbons and trace organics in the sample stream.

One commenter (09) requested clarification on the measurement of the ethylene oxide concentration for the aeration room vent. Specifically, the commenter requested clarification on whether this was a maximum from a single point sample or a maximum average of continuous monitoring of several samples.

One commenter (17) stated that because the 1 ppmv emissions limit can be circumvented by increasing the airflow through the vent, sources required to meet the standard should be required to meet a <1 ppmv concentration and 99-percent control requirement, so that the more stringent limit prevails. The commenter also stated that a concentration measurement that is below the detection limit of 0.2 ppmv should also indicate compliance. One commenter (18) recommended that emissions below the detection limit of the test be considered in compliance.

Response: The Agency recognizes the potential difficulties associated with accurately monitoring the ethylene oxide concentration on a continuous basis. In the final rule, the Agency has provided sources the flexibility to monitor the ethylene oxide concentration or to monitor control device parameters that provide continuous monitoring of compliance. If the source chooses to measure ethylene oxide concentration in its monitoring program, then the ethylene oxide concentration for the aeration room vent shall be measured hourly and averaged over three 1-hour measurements. The aeration room vent standards specify that this concentration shall be 1 ppmv or less for affected sources. Measurements of ethylene oxide below the detection limit are considered to be in compliance.

2.4.8 Monitoring Requirements in General

Comment: Six commenters (05, 06a, 09, 11, 16, 19) provided general remarks regarding monitoring requirements. One commenter (05) stated that each operator of a commercial sterilization facility should be able to demonstrate compliance by establishing

during the initial performance test the operating parameters of their systems (including control technologies) that will achieve compliance, validate those parameters, and then operate to those parameters and use the procedures outlined in § 63.366 to report deviations. The commenter added that if compliance could not be demonstrated in this manner then additional controls (scrubbers, catalytic oxidizers, etc.) would be in order. One commenter (17) recommended that the final rule consider the entire control device as a whole and that appropriate compliance demonstrations and other considerations be determined on a case-by-case basis where new technologies or hybrid systems are employed. One commenter (18) recommended that the owner/operator of a source seeking to demonstrate compliance with some other control scenario be allowed to establish an appropriate range for the parameters, with the approval of the implementing agency; operation precisely at the conditions established during the performance test may not be practical for normal operating conditions.

One commenter (06a) suggested that a facility should be given the opportunity to validate a process and stay within set operating parameters. The commenter's proposal incorporated an early detection set point that would be established for emissions controls which, in turn, would trigger an alarm notifying personnel of the need for corrective action. The commenter added that process validation cycles could be established annually. The commenter stated that reliance on a continuous monitoring system susceptible to delivering erroneous data could ultimately lead to the unnecessary discontinuation of sterilization of critical life saving medical devices and higher overall cost of medical care. Two commenters (17 and 18) requested that facilities employing an interlock system that shuts down the entire system and prevents the sterilizer from being used in the event that the conditions in the catalyst bed are outside of the acceptable range be exempted from the proposed monitoring, recordkeeping, and compliance provision requirements. One of these commenters (17) suggested that such facilities be required

to record incidences of interlock shutdown and recharging of the bed.

One commenter (09) stated that the proposed monitoring requirements would result in at least $100,000 in capital expenditures for one of the commenter's facilities. The commenter estimated that the monitoring and the submittal of reports would result in approximately $50,000 in annual costs. The commenter also stated that because they also rely on contract sterilizers, their product costs would be significantly increased by this regulation.

Response: The Agency has considered allowing interlock systems in lieu of the monitoring requirements presented for catalytic oxidizers. While the EPA wishes to encourage innovative technologies such as interlock systems, the EPA has insufficient information on the variety of designs and applications of interlock systems to specify alternative monitoring, recordkeeping, and compliance procedures that would be appropriate for all such systems. Sources wishing to use interlock devices may apply to the Administrator as described in the General Provisions § 63.8(f) and in § 63.365(g) of the final rule. In regards to establishing a set point that notifies personnel of system malfunctions, the Agency does not believe that it is appropriate to specify requirements for "triggers" in the standards. Rather, the Agency believes that the establishment of any such triggers or set points should be left to the owners or operators of an affected source.

The Agency agrees with the commenters that compliance should be measured during the initial compliance test and that the source should be allowed to show compliance with the emissions standards through a control scenario of the source's choice. The Agency has provided monitoring requirements and compliance provisions for the most commonly used control devices (i.e., the referenced control technologies) but has also incorporated provisions for sources using alternative controls (§ 63.365(g) of the rule and § 63.8(f) of the General Provisions). However, the Agency believes that sources should not be allowed to establish

their own operating parameters and to monitor parameters of their choice unless the source has applied to the Administrator for approval of such plans. The parameters to be monitored under the final rule for the referenced control technologies have been selected by the Agency to assure compliance with the standards and to standardize reporting of noncompliance. In instances where a referenced control technology is used, the parameters detailed in the rule should be used for monitoring. The Agency understands that allowing sources to select parameters to be monitored for compliance provides flexibility to the source; in instances where the control scenario used at the source does not match those referenced in the rule, the source must develop a comparable compliance and monitoring plan and apply to the regulating Agency for approval. However, the Agency believes that the approval process that would ensue from the commenter's suggested compliance program for all facilities would result in a lessor indication of compliance with the standards, additional time expended by sources for developing individual compliance programs, and an additional review step in the regulating Agency's approval process for these compliance plans. The Agency believes that the additional step in the approval process would overwhelm the regulating agencies.

The owner or operator of the commercial ethylene oxide sterilization and fumigation operation seeking to demonstrate compliance with the standards using an alternative control device may submit a monitoring scenario utilizing a range for the monitored parameters, however, any such submittal will be subject to review and possible modification by the Administrator. Regarding the commenter's request that the Agency consider the entire control device as a whole, the Agency asserts that this is how the compliance determinations and monitoring requirements in the proposed rule and final rule were determined. In evaluating any submitted alternative compliance provisions or monitoring requirements, the Agency will attempt to also consider the control device as an entire unit. In regard to the commenter's statement on the practicality of operation of the source at the

precise conditions as were established during the performance test, the Agency is promulgating monitoring requirements in the final rule that show compliance at all times of operation.

The Agency appreciates the information on the cost of compliance submitted by the commenter. In the final rule, the Agency has provided additional flexibility to affected sources that the Agency believes will reduce the costs of compliance without affecting the effectiveness of the monitoring program.

Comment: One commenter (19) agreed with EPA's proposed point-by-point compliance scheme.

Response: The Agency appreciates the commenter's support.

2.5 TEST METHODS

Comment: Three commenters (04, 05, 11) made suggestions regarding the test methods identified in the regulation. These commenters (04, 05, 11) referred to background documents that state high reactivity (04), low concentrations of ethylene oxide, high temperature, and presence of moisture do not provide reproducible, accurate results (04, 05, 11); one commenter (05) stated that Method 18 is not practical for hourly sampling and another commenter (11) stated that continuous monitoring of ethylene oxide is not obtainable. One commenter (05) asked that an alternative to Method 18, Section 7.2, for the aeration room vent standard as specified in § 63.365(c) be identified due to these factors. Another commenter (11) suggested that the requirement in § 63.365(a)(3)(ii)(A)(1) to have sample bags analyzed within 8 hours should be consistent with § 63.365(a)(3)(ii)(B)(1), which requires that samples be analyzed within 24 hours.

Response: The Agency has included alternative compliance provisions and monitoring requirements in the final rule to provide affected sources with additional flexibility to assure compliance with the standards. The Agency agrees that parametric monitoring of the control device used for the aeration room vent and chamber exhaust vent should be allowed as an alternative to direct measurement of the ethylene oxide concentration in the stream with Method 18, Section 7.2. Additional discussion of

this issue and the compliance test procedures is located in Section 2.4. It is assumed that the commenter is referring to §§ 63.365(a)(4)(ii)(A)(1) and 63.365(a)(4)(ii)(B)(1) of the proposed rule (since the sections mentioned did not exist in the proposed rule) [§§ 63.365(b)(1)(iv)(B)(1)(a) and 63.365(b)(1)(iv)(B)(2)(a) in the final rule]. However, the sections mentioned by the commenter each indicate an 8 hour limit on the time allowed before analysis should occur.

Comment: One commenter (17) suggested that under § 63.365(a), the flow rate and concentration be measured at both the inlet and the outlet to the control device to avoid possible errors including air leaks into the sterilization chamber, leaks from the vacuum pump, and errors that could occur if the inlet ethylene oxide concentration is measured directly but the flow is not measured (i.e., the mass of ethylene oxide fed to the abater must be derived, potentially not taking into account the combustion air added to catalytic oxidizer units). Another commenter (18) stated that the method for determining residual mass of ethylene oxide in the sterilization chamber (§ 63.365(a)(2), based on the ideal gas law) does not consider air leaking into the chamber during initial evacuation. This commenter also stated that the total mass of ethylene oxide (Wi) at the inlet to the control device is not measured directly, and is therefore subject to error. The commenter recommended that the concentration and flow rates be measured at the inlet and the outlet.

Response: Section 63.365(b)(1) of the final rule allows the source two options for calculating the total mass of ethylene oxide at the inlet to the control device: (1) calculating the theoretical mass charged to the chamber by utilizing one of several techniques listed; or (2) by measuring the flow rate and concentration of ethylene oxide by utilizing the techniques to be used at the outlet of the control device. The Agency allowed the use of theoretical calculations for inlet mass in order to minimize exposure of the source tester to ethylene oxide.

Comment: One commenter (18) recommended that EPA provide an expedited mechanism via Subpart E to approve alternative test methods and monitoring protocols, or delegate approval of same to State/local agencies for area sources.

Response: The Agency believes that facilities choosing an alternative test method or monitoring method than those specified in the standard should follow the requirements as specified in §§ 63.7 and 63.8, i.e., apply for approval of such plans to the Administrator, of the General Provisions. The Agency believes the requirements as established in the General Provisions are sufficient for approving use of alternative plans for this regulation. Following the implementation of Part 70, the Agency believes that States may be delegated the authority to implement the provisions of Part 63 standards.

2.6 REPORTING AND RECORDKEEPING REQUIREMENTS

2.6.1 General

Comment: One commenter (18) agreed with the limited recordkeeping and administrative requirements for facilities that qualify for the low usage exemption [i.e., sources <1 ton/yr].

Response: The Agency recognizes the burden recordkeeping places on small sources and has therefore limited the requirements for these sources to alleviate this burden. Many of the requirements of the General Provisions are specific for major sources, and some are not appropriate for area sources in this source category. Several of these requirements, such as construction/reconstruction requirements, performance test plan requirements, and performance evaluation test plan requirements for monitoring equipment, have been waived for area sources.

In addition to these exemptions, all sources (both major and area) in this source category have been waived from the requirement to develop a startup, shutdown, and malfunction plan as specified in § 63.6 of the General Provisions. Due to the batch nature of the industry, the Agency does not foresee emissions associated with startup, shutdown, or malfunction periods that would affect the source's compliance status. No emissions are associated with startup of the process (i.e.,

introducing ethylene oxide into the sterilization chamber); emissions associated with shutdown of the process are vented to control equipment and, in the instance of a malfunction of the control equipment, the process may be stopped (i.e., no ethylene oxide emissions) until the malfunction has been corrected. While the Agency has not required sources to develop a plan, a source may choose to voluntarily develop a startup, shutdown, and malfunction plan if they have a concern regarding the source's compliance status due to ethylene oxide being emitted during startups, shutdowns, and malfunctions.

2.6.2 Relationship to the General Provisions

Comment: Two commenters (04, 05) stated that §§ 63.366(b) and (c) should be modified to conform with § 63.9 (Notification Requirements) of the final General Provisions.

One commenter (18) stated that the initial notification should be required no sooner than 120 days after the effective date in order to allow all facilities to receive and comprehend the Federal Register notice containing the final rule.

Response: The General Provisions were finalized on March 16, 1994, following the proposal of these NESHAP. The recording and recordkeeping requirements of the final rule will be made consistent with the General Provisions. A table identifying the applicable, modified, and nonapplicable requirements of the General Provisions has been included in the final rule.

2.6.3 Reporting Frequency

Comment: One commenter (18) recommended that implementing agencies be allowed to determine the frequency of reports based on individual program needs and routine inspection schedules.

One commenter (13) recommended that an excess emissions and monitoring system performance report be submitted every quarter, and if there have been no exceedances, the facility should state this.

Response: The Agency has determined that semiannual reporting is appropriate for this regulation; however, a source may be subject to more frequent reporting if the Administrator

determines it is necessary for a particular source. In addition, excess emissions reports must be submitted semiannually even when no excess emissions have occurred. The EPA recognizes the value of reporting on a regular basis in that the source demonstrates their attention to applicable standards. By requiring sources to report violations on a regular basis, the enforcement authority is able to identify potential violations in a timely manner. Since penalties are calculated per day per violation, the timely identification of violations reduces a source's liability. More importantly, timely identification allows the enforcement authority to ensure that the cause of a violation has been addressed, thereby reducing potential health effects of the emissions. In addition, companies that have facilities in several States could possibly be subject to numerous different and confusing reporting schedules.

2.7 WORDING OF THE REGULATION

Comment: Three commenters made suggestions regarding the wording of the regulation. One commenter (13) suggested that the definition for the term "baseline ethylene glycol concentration" be amended as follows: "baseline ethylene glycol concentration means the maximum concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device beyond which the scrubber achieves less than 99 percent control of ethylene oxide emissions." This commenter also suggested that § 63.363(a), Compliance and Performance Testing, be reworded as follows: "The emissions limits of this subpart apply at all times except that, during periods of malfunction which might increase emissions, no ethylene oxide shall be charged to the affected sterilization chamber during the malfunction." Another commenter (14) stated that the regulation should avoid confusion between the terms "baseline temperature," "combustion temperature," and "temperature of catalyst bed." An appropriate definition of "baseline temperature" would be as follows: "baseline temperature" means the temperature at the inlet of the catalyst bed in a catalytic oxidation unit control device at which the unit achieves at least 99 percent control of ethylene

oxide emissions. Another commenter (18) stated that the definition for the term "chamber exhaust vent" should only refer to a physical emissions point, not a time period during which that point meets the definition. The standard for the chamber exhaust vent could include the time-frame during which the standard applies.

Response: The definitions for baseline ethylene glycol concentration and baseline temperature have been revised in the final rule. The definition for chamber exhaust vent has not been revised because reference to both the physical point and the time period are significant in defining this term. Interchangeable use of the different temperature terms has been eliminated and the term baseline temperature is used consistently in the final rule. Changes to the wording of § 63.363 for applicability during malfunctions have been incorporated.

Comment: One commenter (18) suggested several clarifications for § 63.360: (1) eliminate § 63.360(a); (2) eliminate § 63.360(b) and include the language of this exemption in the aeration room vent standard; and (3) rephrase § 63.360(c) to refer to sources that are subject to the standard rather than those that are not. Another commenter (17) indicated that a separate applicability threshold for aeration room vents should be included in § 63.362(b), as follows: "Aeration room vent. Each owner or operator of an existing or new sterilization facility that uses 9,070 kilograms (kg) (10 tons) of ethylene oxide within any consecutive 12-month period, shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent . . . ."

Response: Section 63.360 of the final rule identifies the applicability of the regulation to specific commercial sterilization and fumigation sources. Language has also been added as suggested to the standards in § 63.362 of the final rule to identify those sources that are subject to a specific standard. The Agency believes that the applicability section and the emissions standards in the final rule have been written clearly.

2.8 MISCELLANEOUS

Comment: Two commenters (07, 13) questioned why the proposed regulation was not included along with the preamble in the Federal Register. One of these commenters (07) also questioned whether this form of notice satisfies EPA's obligations for informed notice and comment for rulemaking. The other commenter (13) stated that omission of the text of the proposed regulation is not a good policy. This commenter explained that requesting a copy of the rule from EPA through the mail would take time out of the already limited comment period and explained that downloading from the TTN requires access to a computer, modem, and appropriate software. The commenter stated that these methods of obtaining the actual text of the proposed regulation could be difficult for some facilities, especially small facilities, and added that it is critical that facilities know when the proposal date occurs since the regulations will apply to new sources from this date onward. This commenter also suggested that until EPA revises this policy, the fact that the actual proposed regulation is not included in the Federal Register notice should be made very clear, and an EPA contact person, their telephone number, and the TTN telephone number should be included. One commenter (07) indicated that the text of the proposed regulation is equally, if not more, important than the preamble, and the other (13) stated that it makes more sense to leave out the preamble and to print the regulation.

Response: The Agency has reviewed its responsibility to adequately inform the affected public of proposed actions. The decision to reduce the amount of printed material in the Federal Register and assure that the material, including the proposed regulatory text of the proposed rule, is accessible for public comment and judicial review does not conflict with the statutory requirements of the Administrative Procedures Act (APA), the Federal Register Act (FRA), nor the requirements of the Clean Air Act Amendments of 1990. Access to material that is used as the basis of the proposed rule (officially located in the

Air Docket created by the CAAA) is identified in the preamble to the proposals and promulgations of rules. Specifically, the Agency clearly established and will continue to look for additional connections and will include directions for obtaining the text of information not printed in the Federal Register. Currently, this information may be obtained through one of the following sources: (1) the TTN's "Recently Signed Rule" bulletin board; (2) directly from the Air and Radiation Docket and Information Center; (3) distribution to trade associations; (4) plaintiffs in court ordered regulatory actions; (5) contact with small business ombudsman system in each State; and (6) if necessary, through the contact person at the Agency. The response to this approach has been positive as the process has aged.

The proposal date is the date that the notice of the Agency's action is signed by the Administrator and published in the Federal Register. This has always been the case with the Agency's rulemakings. The printing of the regulatory text does not depend on the effective date of applicability as determined by the date of Federal Register publication.

The Agency believes that all information that is developed in the course of the development of a proposed and final rule is important, however, EPA believes they have realistically and responsibly addressed the need to publish information in the Federal Register. The Agency will continue to review the issue of extensive publishing in the Federal Register along with its responsibility to adequately inform affected parties of our proposed and final actions.

Comment: One commenter (03) suggested that the rule include the standards in the form of a table.

Response: The Agency agrees that providing the requirements of the standards in tabular format is a convenient summary method. Tables similar to those presented in the preamble to the proposed rule have been included in the final rule to supplement the regulatory text.

Comment: One commenter (02) requested that EPA promulgate the final rule for this source category by November 15, 1994; promulgation by the scheduled date is important to the States who have the obligation of implementing and enforcing the NESHAP standards and requirements.

Response: As a result of a Clean Air Act litigation suit, Sierra Club v. Browner, the proposal and promulgation dates for several NESHAP were agreed upon in a consent decree. The commercial sterilization and fumigation facilities source category was included in this consent decree and the court-ordered deadline for promulgation of this NESHAP is November 23, 1994. The EPA will promulgate this project on schedule.

Comment: One commenter (10) stated that emissions averaging does not address the possible health effects from exposure to high concentrations of an extremely toxic substance for a short time period.

Response: The EPA does not believe emissions averaging can be used practically for commercial sterilization facilities and has not included emissions averaging in the final regulation. The Agency could not develop a credible averaging scheme and requested comment in the preamble to the proposed rule on the feasibility of emissions averaging for this industry and also requested submittal of potential emissions averaging schemes from commenters. None of the commenters submitted an averaging scheme to the Agency.

Comment: One commenter (08) indicated support for the stated positions of commenter 11.

Response: The Agency appreciates this commenter's support for statements made by commenter 11.

Comment: One commenter (06b) noted that CFC's and HCFC's that are used as a diluent with ethylene oxide in commercial sterilization inhibit the efficiency and can cause permanent damage to catalyst in catalytic oxidizers. The commenter added that there is typically a much higher proportion of CFC/HCFC's relative to ethylene oxide in the sterilant gas. The commenter

also noted that the CFC/HCFC's will produce toxic byproducts including phosgene at oxidation temperatures above 400°F.

Two commenters (17 and 18) stated that EPA should consider the existence of multiple control units on a single vent. The commenters were aware of a number of sources that have installed membranes or condenser/compressor units (whose performance can vary considerably) between the sterilization chamber and the abatement device to collect ethylene oxide and CFC's. The commenters specifically noted these devices as they relate to varying ethylene oxide concentrations and hence temperature responses when catalytic oxidation is used for abatement.

One commenter (19) stated that EPA should address the implications of CFC phase out as it relates to potential increased ethylene oxide emissions, especially from sources falling below the proposed 1 ton/yr ethylene oxide use cutoff.

Response: The Agency is aware of the use of CFC's and HCFC's as dilutants for ethylene oxide in commercial sterilization and the potential impacts associated with catalytic oxidation of CFC-EO mixtures. As noted in the Background Information Document for these proposed standards, the Agency does not believe that toxic CFC byproducts would be emitted following catalytic oxidation because the CFC's do not react at the temperatures typically occurring during catalytic oxidation (150° to 180°C [300° to 350°F]). The Agency has also been made aware that the use of EO-CFC gas mixtures has significantly decreased in response to increased regulation of CFC's. The Health Industry Manufacturer's Association (HIMA) has informed EPA that none of their members are currently using EO-CFC gas mixtures.

Use of multiple controls, ex. installing membranes or condensers prior to the control device, is at the source's discretion as long as the control efficiency achieved by the multiple control units is consistent with the applicable standard. A source, however, would be required to apply to the Administrator for approval of the monitoring plan for the control scenario.

The EPA would like to point out that increased emissions of ethylene oxide should not result from CFC phase out. Because the sterilization process must be performed using a specified concentration of ethylene oxide, the same amount of ethylene oxide is used for a sterilization process whether pure ethylene oxide or 12/88 is used. The Agency believes these NESHAP are sufficient to control ethylene oxide emissions from all affected area and major sources.

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15. SUPPLEMENTARY NOTES

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16. ABSTRACT

National emissions standards to control emissions of ethylene oxide from new and existing sterilization/fumigation operations are being promulgated under Section 112 of the Clean Air Act. This document contains information on the background and authority, a summary of public comments and Agency responses, and a summary of changes to the regulation following proposal and the resulting environmental and economic impacts.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
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